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Part III

Department of Health and Human Services

Health Care Financing Administration
Public Health Service

42 CFR Part 493

Clinical Laboratory Improvement Amendments of 1988; Final Rules and Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 493

[HSQ-177-FC]

RIN 0938-AE28

Clinical Laboratory Improvement Act Program Fee Collection

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule with comment.

SUMMARY: This rule implements provisions of section 353 of Public Health Service Act (as amended by the Clinical Laboratory Improvement Amendments of 1988). Those provisions require laboratories to pay fees for issuance of registration certificates, certificates of waiver, certificates of accreditation, or certificates and to fund activities to determine compliance with the requirements established by the Department of Health and Human Services for laboratory testing. It also establishes the policy that laboratories licensed by and located in States with licensure programs approved by HHS may be exempt from the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). This rule also establishes the methodology used to determine the amount of the fees charged for certificates of waiver, registration certificates, certificates of accreditation, or certificates and activities to establish application procedures and determine compliance with applicable certification requirements.

DATES: *Effective date:* These regulations are effective March 30, 1992. They are being issued as a final rule with comment for reasons explained under "Supplementary Information," in section VII, "Final Rule with Comment Period."

Comment period: We will accept comments on the collection of fees related to State-exempt laboratories from the respective States. Comments on this issue only will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on April 28, 1992.

ADDRESSES: *Comments:* Mail written comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HSQ-177-FC, P.O. Box 26676, Baltimore, MD 21207.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201, or

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland 21207.

Due to staffing and resource limitations, we cannot accept audio or video comments or facsimile (FAX) copies of comments. In commenting, please refer to file code HSQ-177-FC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in room 309-G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 245-7890).

Questionnaires: While the law places the responsibility to apply for a certificate on the entity that conducts laboratory testing, to facilitate the initial phase of implementation, we have mailed questionnaire materials to all affected entities that we could identify to solicit initial information. If an entity that conducts laboratory testing has not yet received a questionnaire, write to the following address to obtain one: HCFA Laboratory, P.O. Box 26687, Baltimore, MD 21207.

Copies: To order copies of the **Federal Register** containing this document, send your request to the Government Printing Office, Attn: New Order, P.O. Box 371954, Pittsburgh, PA 15250-7954. Specify the date of the issue requested and stock number 069-001-00042-4. Enclose a check payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 783-3238 or by faxing to (202) 512-2250. The cost for each copy is $3.50. In addition, you may view and photocopy the **Federal Register** document at most libraries designated as U.S. Government Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**. Ask the order desk operator for the location of the U.S. Government Depository Library nearest to you.

FOR FURTHER INFORMATION CONTACT: Jeffrey A. Clark (410) 966-6802.

SUPPLEMENTARY INFORMATION:

I. Background

A. Federal Oversight

Before the establishment of the Health Care Financing Administration (HCFA) in 1977 and the signing of an interagency agreement, the Public Health Service (PHS) was responsible for the administration of the Clinical Laboratories Improvement Act of 1967 (CLIA '67). Currently, HCFA has inspection and administrative responsibility for both the Medicare and CLIA programs. HCFA and PHS have the joint responsibility for the development of the Federal requirements for laboratories. Within the PHS, the Centers for Disease Control (CDC) and the Food and Drug Administration (FDA) provide technical and scientific expertise in the establishment of regulations.

B. Legislative History

Prior to the enactment of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, laboratories engaged in testing specimens in interstate commerce were required, under CLIA '67, to meet the requirements of section 353 of the Public Health Service Act (42 U.S.C. 263a). In October 1988, Public Law 100-578 amended section 353 of the Public Health Service Act (PHSA) to expand the authority for the regulation of laboratories, with some provisions having varying effective dates depending on whether or not the laboratory was subject to CLIA '67 on December 31, 1988. The provisions that are the subject of this rule have the following effective dates: The fee provisions (section 353(m) of PHSA) are effective January 1, 1989 for all laboratories; the application provisions (section 353(d) of PHSA) are effective January 1, 1990 for all laboratories; the provision in section 353(g)(2) relating to inspection and the provision in section 353(f)(1)(C) relating to personnel qualifications are effective January 1, 1990 for laboratories that were subject to CLIA '67 on December 31, 1988, and on July 1, 1991 for all other laboratories.

Prior to the 1988 amendments, only those laboratories performing interstate testing were subject to the provisions of CLIA '67. CLIA '67 included a provision that authorized the Secretary of the Department of Health and Human Services (HHS) to collect fees from approved laboratories for the issuance and renewal of CLIA licenses. The fee was set at $25 for each test category with a $125 cap on the amount any laboratory would be required to pay. This fee was eliminated because the administrative costs required for collection exceeded the revenue derived from the fees.

The 1988 CLIA amendments require that any entity performing laboratory testing have a certificate, certificate of

accreditation, or certificate of waiver or be licensed by an approved State licensure program (that is, State-exempt) and comply with the standards for laboratory testing established by HHS. In addition, section 353(m) of the PHSA, as amended by CLIA, requires HHS to impose fees for the issuance and renewal of certificates, certificates of waiver, and accreditation certificates and for determining program compliance. Although the fee required for issuance and renewal of a certificate of waiver is to be only a nominal fee, the overall fees for certificates and certificates of accreditation must be sufficient to cover the general costs of administration incurred by HHS in carrying out the provisions of section 353 of the PHSA, including evaluating and monitoring approved proficiency testing programs and accreditation bodies and implementing and monitoring compliance with the requirements of section 353 of the PHSA. The fee imposed for determining compliance must also be sufficient to cover the costs incurred by HHS in inspecting laboratories that are not accredited. Section 353(m) also requires that the fees imposed vary by group or classification of laboratory, based on such considerations as HHS determines are relevant.

HHS is also required, under section 353(n) of the PHSA, to annually compile and make available to physicians and the general public information that HHS determines is useful in evaluating the performance of a laboratory. This information must include a listing of laboratories whose certificates have been revoked, suspended, or limited and those laboratories that have been subject to intermediate sanctions, exclusion from Medicare or Medicaid, injunctions, or withdrawal of accreditation. Additionally, sections 353(e)(2)(D) and 353(e)(3) of the PHSA require HHS to evaluate annually the performance of each approved accreditation body and submit an annual report to Congress that describes the results of that evaluation.

Section 6141 of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239) requires that laboratories participating in the Medicare program comply with CLIA requirements. Only laboratories that have a current unrevoked and unsuspended certificate of waiver, registration certificate, certificate, or certificate of accreditation, or are State-exempt will be eligible for reimbursement in the Medicare or Medicaid programs or both.

On August 3, 1990, we published our proposed rule (55 FR 31758) to implement the certificate and fee requirements of CLIA.

II. Implementation of CLIA

The following is a general explanation of our plan to implement CLIA, as well as CLIA's relationship to Medicare and Medicaid.

A. Activities to Date

In order to implement CLIA, in addition to this final rule, we published three proposed rules. The three proposed rules are:

HSQ–176–P Medicare, Medicaid and CLIA Programs: Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA)

This proposed rule was published on May 21, 1990, with the comment period closing on September 21, 1990. It set forth our proposed requirements for laboratories that must be inspected, as well as the criteria for determining if a laboratory qualifies for a certificate of waiver. In addition, this proposed rule outlined how laboratories would be regulated as a function of the complexity of tests and their risk of harm to the patient if mistakes were made in testing. Provisions include requirements dealing with personnel, quality control, quality assurance, proficiency testing, and recordkeeping, among others. These provisions will also be used as the basis of comparison of State or private accreditation program requirements when organizations are seeking deemed status under the law or States are seeking an exemption. This regulation generated 60,000 comments. The final rule is published in this edition of the **Federal Register**.

HSQ–179–P Medicare and Clinical Laboratory Improvement Amendment Programs: Enforcement Procedures for Laboratories

This proposed rule, which was published on April 2, 1991, outlines how the Federal Government proposes to implement the provisions of section 1846 of the Social Security Act, as amended by section 4064(d) of the Omnibus Budget Reconciliation Act of 1987 and sections 353(h), (i), (j), (k), and (l) of the PHSA. This rule applies to laboratories that are subject to CLIA or that participate in Medicare/Medicaid. The final version of this proposed rule is published in this edition of the **Federal Register**.

HSQ–181–P Clinical Laboratories Improvement Amendments Program: Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and State Licensure Agencies

The CLIA law (at sections 353(e) and (p) of the PHSA) permits States and private, nonprofit accreditation organizations to seek our approval of their programs. A laboratory that is accredited by an approved State or private accreditation program would be "deemed" to meet CLIA requirements. (Note that, as a change from the requirements outlined in HSQ–177–P, a laboratory licensed in a State whose licensure program is approved would be exempt from CLIA requirements). The proposed rule, published on August 20, 1990, with the comment period closing on October 19, 1990, sets forth the criteria we would use to approve and to withdraw approval of State or private accreditation programs.

B. Sequence of Implementation Events

CLIA requires that all laboratories in the United States subject to its provisions be regulated by the Federal Government. Regulation is mandated regardless of whether or not a laboratory is being reimbursed for services by the Federal or State government. CLIA legislation requires that such regulation focus on the issuance of a certificate, without which a laboratory may not legally test human specimens for the purpose of "providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings." The publication of this final rule concerning application procedures and fee schedules is a first step in the full implementation of CLIA. After considering comments received in response to the proposed rule, we have decided to adopt the following implementation plan.

1. Mailing of Questionnaire

The law requires every laboratory subject to the provisions of CLIA to hold a certificate issued by HCFA. Initially, we sent a questionnaire to entities performing laboratory testing soliciting basic information concerning the name and address of the laboratory, the type of ownership, type of facility, name of director, types of personnel, test volume by specialty and subspecialty, and test methodologies and reagents. All laboratories subject to CLIA must complete the questionnaire so that HCFA is provided with information on laboratories performing testing that can

be used by HCFA to develop a database.

To determine the entities that received the questionnaire, HCFA took a number of actions. These included mailings to professional groups and State licensing components to request their assistance in identifying facilities affected by CLIA, and advertising (though a variety of trade periodicals and special interest journals) our implementation of the CLIA law and instructions for laboratories to follow to obtain the necessary certificate. If a facility performing laboratory testing has not received a questionnaire from HCFA, it is the responsibility of the facility to request a questionnaire from HCFA. This request should be made to the address previously indicated.

2. Mailing of Applications and Bills

After receipt of the completed questionnaire and publication of the standards rule, HSQ–176–F, we will send an application and a bill for the certificate fee (based on the volume of testing indicated on the questionnaire) to each laboratory that we believe (based on the information provided in response to the questionnaire) is subject to the requirements of CLIA. Mailing after publication of the final standards rule will allow laboratories sufficient time to review the standards and criteria established by HSQ–176–F and determine whether they want to continue testing based on the standards.

3. Issuance of Registration Certificate or Certificate of Waiver

Upon receipt of the completed application and fee, we will issue a registration certificate or certificate of waiver. (In this final rule, we are using the term "registration" certificate(s) in place of "provisional" certificate(s) in order to accurately reflect the fact that this type of certificate represents only the registration of the laboratory and does not indicate a certification of quality. This change is reflected throughout the preamble and regulation.) If upon review of the information provided by a laboratory in the application, we determine the laboratory qualifies for a certificate of waiver, we will issue a certificate of waiver to the laboratory instead of a registration certificate. If we find that the fee amount that the laboratory was billed and paid is greater than the fee for a certificate of waiver, a refund of the difference will be made to the laboratory. No fees will be collected from existing laboratories electing to discontinue laboratory testing before the effective date of the standards rule HSQ–176.

The registration certification indicates that the laboratory has properly registered with the government and is legally entitled to test human specimens and to conduct business and agrees to comply with CLIA requirements. The registration certificate will remain in effect for up to 2 years, although the registration certificate may be re-issued if additional time is necessary for HHS to conduct an inspection; or pending an appeal. This will ensure that the laboratory has a valid certificate authorizing the testing of human specimens. The registration certificates will be effective until we are able to conduct inspections, approve State programs and private accreditation programs (deemed status), and determine which laboratories qualify for certificates.

4. Final Implementation Steps

As final implementation steps, we will:

- Approve (or disapprove) private nonprofit accreditation programs for deemed status.
- Approve (or disapprove) State licensing programs for exemption of their laboratories from the requirements of CLIA.
- Communicate with all laboratories that hold registration certificates, instructing them on how to apply for a regular certificate, certificate of waiver, or certificate of accreditation, whichever applies. The laboratory will be billed for the appropriate certificate and compliance fees and, if an inspection to determine compliance is necessary, it will be scheduled and conducted. The laboratory will be required to submit the billed amount to HHS prior to the determination of compliance (including inspection). The inspection, if required, will be performed generally by State surveyors who will determine, with the assistance of guidelines developed by us, if the laboratory successfully meets CLIA's requirements. If the State survey agency determines that the laboratory meets CLIA's requirements, it will recommend that we issue a certificate. This (regular) certificate indicates that the laboratory has demonstrated that it has met all of the conditions and standards outlined in CLIA. A laboratory that meets the requirements for a certificate of waiver and has submitted the appropriate fee will not be subject to routine inspection.
- Implement procedures for the reissuance of certificates upon expiration. A certificate will be valid not more than for 2 years. Prior to the expiration date of the certificate, HHS will send an application to the laboratory and collect the necessary fee(s), and the compliance determination survey cycle and certificate issuance will be repeated.
- Establish and maintain a computer system to manage the above processes.
- Implement the system of alternative sanctions and enforcement procedures described in the law and the final version of HSQ–179.
- Continue to conduct the mandated studies and make reports to Congress concerning the implementation of CLIA.

C. Implementation of Certificates of Accreditation

If, after HHS has approved accreditation programs, a registered or certified laboratory seeks a certificate of accreditation, the laboratory must show proof of accreditation by an approved private accreditation body or proof that the laboratory has applied for such accreditation. We will allow the laboratory up to 11 months to receive accreditation. If the laboratory is not accredited by then, we will notify the laboratory that it is subject to Federal inspection, and include a bill for the inspection costs. We believe 11 months from the time application for accreditation is made is adequate time for accreditation to take place.

While the approved accreditation body will bill the laboratory separately for its inspection and any other fees applicable, we will send an accredited laboratory a bill for a registration certificate (if necessary) and/or a certificate of accreditation to cover our administrative costs and the costs of monitoring the performance of approved private accreditation bodies as required by CLIA.

D. State-Exempt Laboratories

If a laboratory is licensed by and located in a State that has had its licensure and inspection program approved by HHS under section 353(p) of the PHSA, the laboratory is exempt from CLIA's requirements and, therefore, need not apply for certification, pay any certificate fee(s), or undergo a routine onsite CLIA compliance determination survey. These "State-exempt" laboratories are subject, however, on a sample basis, to surveys to determine the extent and appropriateness of the State's licensing criteria. For purposes of establishing a user fee amount for this activity, we considered 5 percent of the State-exempt laboratories an appropriate sample size. State-exempt laboratories will not receive certificates or pay fees. Rather, HHS may assess their State licensing programs fees for all validation

surveys conducted and any follow-up visits that may be necessary.

III. Provisions of the Proposed Rule

We proposed to implement section 353(m) of the PHSA by establishing regulations at 42 CFR part 493, subpart F. We proposed the requirements all laboratories must meet in order to apply for and be issued a certificate under CLIA and proposed the methodology for determining the amount of the fees for issuing provisional certificates, certificates, certificates of waiver, and certificates of accreditation, and for the proposed fee schedules for determining compliance with the standards.

We proposed, in § 493.606, that part 493, subpart F would apply to all entities that perform laboratory testing, except that it would not apply to any component or function of a laboratory that has been certified by the National Institute on Drug Abuse (NIDA) under Executive Order 12564 and section 503 of Public Law 100–71 for the performance of forensic urine drug testing or to laboratories that perform research testing on human specimens but do not report patient specific results for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, an individual patient. If a laboratory conducts both NIDA certified forensic urine drug testing and other laboratory tests, the laboratory would be subject both to NIDA certification for the forensic urine drug testing and these rules for all other tests, including other urine drug testing, performed by the laboratory.

We proposed, in § 493.610, to prohibit solicitation or acceptance of materials derived from the human body for laboratory examination or other procedure unless the laboratory has an effective provisional certificate issued by HHS or a certificate, certificate of waiver, or certificate of accreditation issued by HHS applicable to the specialty or subspecialty of services offered by the laboratory.

In § 493.614, we proposed the procedure a laboratory must follow to obtain a provisional certificate, certificate, certificate of accreditation, or certificate of waiver. We proposed to require that a separate application be made for each laboratory location using a form(s) prescribed by HHS and that the application be signed by the owner, operator, or authorized representative of the laboratory.

Based on section 353(d)(1)(A) of the PHSA, the application would require information that describes the characteristics of the test procedures and examinations performed by the laboratory including—

(a) The names of the test procedures and examinations performed and the total number of test procedures and examinations performed annually;

(b) The methodologies for the test procedures and examinations performed; and

(c) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the test procedures and examinations.

We specifically requested public comment on ways to minimize the reporting burden for laboratories, both in initial applications and in updating certificates, while meeting the legislative requirements.

We proposed, in § 493.618, to require that, in submitting an application for a provisional certificate, a certificate of waiver, certificate of accreditation, or a certificate, a laboratory must agree to the following:

(a) To make records available and submit reports to HHS as HHS may require.

(b) To permit routine inspections by HHS as specified in subpart N of part 493, except that the effective date of this requirement for laboratories not subject to section 353 of the PHSA as in effect on December 31, 1988, is July 1, 1991. This requirement would not apply to laboratories issued certificates of waiver.

(c) Except for certificate of waiver laboratories, to treat proficiency testing samples in the same manner as it treats materials derived from the human body referred to it for laboratory examinations or other test procedures in the ordinary course of business.

(d) To provide HHS with satisfactory assurances, through an attestation statement signed by the laboratory owner, operator, or authorized representative, that the laboratory will be operated in accordance with the requirements established by the Secretary under section 353 of the PHSA.

We proposed, in § 493.622, that if HHS denies a laboratory's application for a provisional certificate, certificate, certificate of accreditation, or certificate of waiver or limits its applicable certificate, the laboratory would be given a statement of the grounds on which the denial or limitation is based and an opportunity for a hearing in accordance with procedures set forth in part 498.

We also proposed that if a laboratory that is seeking a certificate of any kind for the first time has its application denied or the applicable certificate limited, it would not be able to conduct business as a laboratory under the PHSA unless the denial or limitation is overturned at the conclusion of the administrative appeals process.

As mentioned in section II.B, we plan to implement interim procedures and policy for the issuance of certificates and collection of fees until we are able to fully implement the requirements of CLIA. In § 493.626 we proposed to issue a provisional certificate to each laboratory that was not licensed under section 353 of the PHSA as in effect on December 31, 1988, provided that the laboratory meets the application requirements and pays the applicable fee. Following the full implementation of CLIA, upon payments of the provisional certificate fee, a provisional certificate would be issued initially to any new laboratory not eligible for a certificate of waiver, including a laboratory that is seeking accreditation, to permit the laboratory to test specimens and to allow time for HHS to determine compliance with the CLIA standards.

We also proposed that a provisional certificate would be valid for a period of not more than 2 years. If necessary, a provisional certificate would be reissued until such time as an inspection to determine program compliance can be conducted or the laboratory demonstrates it qualifies to receive a certificate of waiver or certificate of accreditation. We also proposed that the provisional certificate would not be renewable. However, HHS would reissue a provisional certificate to any laboratory that HHS or its designee has not had an opportunity to evaluate for compliance with the requirements for certification.

We proposed that, prior to expiration of the provisional certificate, HHS would notify the laboratory of the requirements to obtain the appropriate certificate. If a laboratory fails to comply with the applicable requirements as specified in the notification, HHS would suspend or deny Medicare payments, if applicable, and initiate revocation or limitation of a laboratory's provisional certificate and would deny the application for a certificate, certificate of accreditation, or certificate of waiver. In this case, HHS would provide the laboratory with a statement of the grounds on which the revocation and denial is based and with an opportunity for a hearing. If the laboratory requests a hearing, the expiration date of the provisional certificate would be extended until a hearing decision by an Administrative Law Judge (ALJ) is issued. The Medicare payments would be suspended or

denied pending the hearing decision because the Act authorizes termination of payments under Medicare for those laboratories that fail to meet the requirements, with the opportunity for a hearing to occur subsequent to payment suspension or denial. Under CLIA, laboratories that do not meet the requirements would be notified of the basis for noncompliance determination and offered an opportunity for a hearing prior to any adverse action, unless HHS determines that the laboratory's deficiencies are such that they constitute an imminent and serious threat to human health.

In § 493.630, we proposed to issue a certificate to each laboratory that was licensed under CLIA '67 as of December 31, 1988 provided the laboratory meets the application requirements and pays the applicable fees.

In § 493.631, we proposed the requirements for certificates of waiver and, in § 493.632, we proposed the requirements for certificates of accreditation.

We proposed that the certificate, certificate of waiver, or certificate of accreditation issued would be applicable to only those test procedures and examinations performed by the laboratory that were included on the laboratory's application. In accordance with section 353(b) of the PHSA, a laboratory may not perform any test procedure or examination within a specialty or subspecialty that is not included on the laboratory's certificate, certificate of waiver, or certificate of accreditation. Laboratories must notify HHS prior to the performance of any test not included as a waiver test for performance by certificate of waiver laboratories or any test not included on the laboratory's certificate. A laboratory may not perform any "new" test or examination until it has requested and been issued an appropriate revised certificate that covers the examination or procedure. Additionally, we proposed that the laboratory must notify HHS or its designee within 6 months of any deletions and/or changes in methodologies for any test procedure or examination for which the laboratory has been issued a certificate, certificate of waiver, or certificate of accreditation.

We also proposed that HHS will initiate revocation or limitation of a laboratory's certificate, certificate of waiver, or certificate of accreditation for failure to comply with applicable requirements. For those laboratories that were licensed under CLIA '67 or participate in the Medicare or Medicaid programs, the applicable health and safety requirements are contained in part 493. The applicable health and safety requirements implementing CLIA will be published in a separate rulemaking. If a determination is made that the laboratory is not in compliance with applicable requirements, the laboratory would be given a statement of grounds on which the revocation or limitation action is based and an opportunity for a hearing. The effective date of the revocation or limitation would not be earlier than the date of decision by an ALJ, unless we find that conditions at the laboratory pose an imminent and serious risk to human health. In such cases, we would suspend or limit the laboratory's certificate before the hearing is held. Failure to meet the applicable requirements could also result in loss of Medicare approval or intermediate sanctions to be specified in a separate proposed rule.

In the interest of administrative efficiency, we proposed in § 493.634 that a laboratory must notify HHS or its designee within 30 days if changes occur in the laboratory's ownership, name, location, or director.

In § 493.638, we proposed that a laboratory must pay a fee for the issuance of a provisional certificate, certificate of waiver, certificate of accreditation, or a certificate, as applicable. We proposed that the total fees collected must be sufficient to cover the general cost of administering the laboratory certification program, including evaluating and monitoring proficiency testing programs and accreditation bodies and implementing and monitoring compliance with section 353 of the PHSA. For a certificate of waiver, the fee includes the cost of issuing a certificate of waiver, collection of fees, and analyzing applications to determine if a laboratory should be issued a certificate of waiver. For a certificate of accreditation, the fee includes the cost of issuing a certificate of accreditation, collection of fees, and analyses of standards and administrative policies of programs of accrediting organizations. The fees for the issuance of a provisional certificate, certificate of waiver, certificate of accreditation, or certificate will be assessed biennially. (Our proposed methodology for determining the amounts of the fees is discussed later in this preamble.)

We also proposed that the fee would be set annually on a calendar year basis and would be based on schedules, or ranges, of laboratory test volume and scope of specialties tested, with the amounts of inspection fees in each schedule a function of the average hourly rates for the required activities and the average length of time required for the activity. The amount of the fee applicable to the issuance of a provisional certificate or to the issuance or renewal of a certificate would be the fee amount in effect at the time the application is received. Upon receipt of an application for a provisional certificate or an application (or renewal request) for a certificate, certificate of waiver, or certificate of accreditation, we would send the laboratory a notice advising it of the amount of the fee. We also stated our intent to inform the public of the fee amounts each year by publishing a notice containing that information in the Federal Register.

In § 493.639, we proposed that if after a certificate, certificate of accreditation, or a certificate of waiver is issued a laboratory adds services and requests that its certificate or certificate of accreditation be upgraded, or certificate of waiver be changed or eliminated, the laboratory must pay a fee to cover the cost of issuing an appropriate revised certificate. We proposed to base this fee on the actual cost to issue the revision to the laboratory. (Note that an additional fee is also required under § 493.643(e) if it is necessary to fund activities to determine compliance with additional requirements.)

In § 493.643, we proposed that a laboratory that was licensed under section 353 of the PHSA as of December 31, 1988 must pay a fee to cover the cost of determining program compliance. We also proposed that effective July 1, 1991, the other laboratories would be subject to a fee to determine their compliance with Federal requirements. We would not begin collecting this fee from these laboratories, however, until applicable criteria and standards are established in final regulations. Further, the laboratory would not be assessed this fee if it qualifies for a certificate of waiver or certificate of accreditation. We proposed to include in this fee the cost of: conducting onsite surveys, evaluating qualifications of personnel, monitoring proficiency testing, documenting deficiencies, evaluating laboratories' plans to correct deficiencies, and State and Federal surveyor preparation for and attendance at ALJ hearings. Laboratories will not be required to pay the cost of investigating followup surveys and sanction activities if allegations are not substantiated. Although the amount of the fee will be determined annually, inspections will be conducted biennially. Therefore, the fee covers a 2-year period. The proposed methodology used to determine the amount of the fee is discussed later in this preamble.

For purposes of determining the amount of the fee a laboratory that must

be inspected must pay, we proposed to initially establish ten fee schedules. The schedules have been established based on the experience of Federal laboratory surveyors and other experts in HCFA to estimate appropriate parameters for classifying laboratories. In addition, we analyzed data from the Federal government's national data base that captures facility-specific information on laboratories, in an attempt to establish parity among the ten schedules listed.

We analyzed the various sizes and workloads of laboratories that are currently participating in the Medicare/Medicaid program and concluded that the average costs to inspect laboratories of various sizes are represented by the benchmarks set forth. These are averages based on a relatively limited amount of experience since the universe of the total number of regulated laboratories will eventually be much greater. We proposed that, as we obtain experience in future years, we will analyze the data and develop new estimates.

We proposed to define a test as a test procedure or examination for a single analyte. Each profile (that is, group of tests) would be counted as the number of separate procedures; for example, a chemistry profile consisting of 18 tests would be counted as 18 separate test procedures or examinations. We specifically invited comments on the appropriateness of the number of specialties and tests we plan to use as thresholds. We also invited comments on our definition of a test and its feasibility, particularly in the area of quantitative testing.

We also proposed that, for purposes of determining a laboratory's fee schedule classification, the specialties and subspecialties currently used for Medicare, Medicaid, and CLIA '67 would be used initially to describe a laboratory's services.

We also proposed that, if after a certificate is issued, a laboratory adds services and requests that its certificate be upgraded, the laboratory must pay an additional fee if, in order to determine compliance with additional requirements, it is necessary to conduct an inspection, evaluate personnel, or monitor proficiency testing participation. We proposed to base the additional fee on the actual resources and time necessary to perform the activities.

In § 493.645, we proposed that, in addition to the certificate fee, a laboratory that is issued a certificate of accreditation would also be assessed a fee to cover the cost of evaluating individual laboratories to determine overall whether an accreditation program's standards and inspection policies are equivalent to the Federal program. An annual random sample of 5 percent of all accredited laboratories would be inspected in order to compare inspection findings of HHS or its agents with the findings of the accreditation organizations. All accredited laboratories would share in the cost of these inspections. These costs are the same as those that would be incurred when inspecting nonaccredited laboratories.

Additionally, we proposed that if, in the case of a laboratory that has been issued a certificate of accreditation, it is necessary to conduct a complaint investigation, impose sanctions or conduct a hearing, the affected laboratory would be assessed a fee to cover the cost of these activities. Sanction activity costs for State surveyors and sanction activity costs for the Federal Government (which include testimony of Federal experts and costs for ALJs and attorney representation) would be in addition to the certificate of accreditation fee. If a complaint investigation results in a complaint being unsubstantiated or if an HHS adverse action is overturned at the conclusion of the appeals process, the cost of the inspection would not be imposed upon the laboratory. The inspection fee for the complaint investigation would not be assessed until after a laboratory concedes the existence of the deficiencies or an ALJ rules in favor of HHS.

In § 493.646, we proposed to notify laboratories by mail of the appropriate fee(s) and instructions for submitting the fee(s), including the due date for payment and the United States Department of Treasury designated commercial bank to which payment must be made. These fees, when finally calculated, would be nonrefundable, and provisional certificates, certificates of waiver, certificates of accreditation, and certificates would not be issued until the applicable fees have been paid.

Three different entities perform activities related to the issuance or renewal of the various types of certificates and determining program compliance. They are: State survey agencies, Federal agencies, and HHS contractors. In § 493.649, we proposed to establish fee amounts fixed to the schedule in which the laboratory falls, which is related to the average hourly rates established for these three entities and to the average number of hours required to perform the activities. We also proposed the costs to be included in establishing the average hourly rate.

We proposed that the number of hours used to determine the overall fee in each of the schedules initially would be HCFA's estimate of the average time needed by each entity to perform the activities for which it is responsible. We asked for comments from all laboratories on the methodology proposed for establishing the fee amounts for determination of compliance because we propose to use the same methodology to determine fees for laboratories that were not subject to CLIA '67 but will be subject to CLIA '88 determinations of compliance. We also proposed that, as we gain experience using the schedules, we would consider appropriate adjustments to the methodology for assessing fees to ensure that each laboratory is charged the fee amount related to the time and resources needed to determine the laboratory's compliance with the requirements.

On the basis of this methodology, we proposed a fee of $261 for issuing a provisional certificate or a certificate to each laboratory, regardless of its relative size. We also proposed this same fee for issuing a revised certificate. (We are changing this approach in this final rule by stipulating that the fee a laboratory must pay for a registration certificate or a certificate will depend upon the laboratory's scope and volume of testing. A discussion of this change is contained in section IV of this preamble in response to comments under § 493.638, "Registration Certificate and Certificate Fees.")

We proposed that, under the proposed methodology, the average time and cost required to determine compliance during fiscal year 1991 would be as follows:

	Hours	Average [1] hourly rate	Biennial user fee
Schedule A Laboratories:			
Biennial inspection [2]	24	$35	$840
Followup visit or complaint investigation	15	35	525

	Hours	Average [1] hourly rate	Biennial user fee
Sanctions/Hearings	8	35	280
Schedule B Laboratories:			
Biennial inspection [2]	32	35	1,120
Followup visit or complaint investigation	17	35	595
Sanctions/Hearings	9	35	315
Schedule C Laboratories:			
Biennial inspection [2]	40	35	1,400
Followup visit or complaint investigation	19	35	665
Sanctions/Hearings	10	35	350
Schedule D Laboratories:			
Biennial inspection [2]	47	35	1,645
Followup visit or complaint investigation	21	35	735
Sanctions/Hearings	11	35	385
Schedule E Laboratories:			
Biennial inspection [2]	54	35	1,890
Followup visit or complaint investigation	24	35	840
Sanctions/Hearings	12	35	420
Schedule F Laboratories:			
Biennial inspection [2]	61	35	2,135
Followup visit or complaint investigation	26	35	910
Sanctions/Hearings	13	35	455
Schedule G Laboratories:			
Biennial inspection [2]	68	35	2,380
Followup visit or complaint investigation	28	35	980
Sanctions/Hearings	14	35	490
Schedule H Laboratories:			
Biennial inspection [2]	75	35	2,625
Followup visit or complaint investigation	30	35	1,050
Sanctions/Hearings	15	35	525
Schedule I Laboratories:			
Biennial inspection [2]	82	35	2,870
Followup visit or complaint investigation	32	35	1,120
Sanctions/Hearings	16	35	560
Schedule J Laboratories:			
Biennial inspection [2]	The sum of 82 hours plus 7 hours for each additional 500,000 tests or portion thereof multiplied by a $35 hourly rate.		
Followup visit or complaint investigation	The sum of 32 plus 2 hours for each additional 500,000 tests or portion thereof multiplied by a $35 hourly rate.		
Sanctions/Hearings	The sum of 16 hours plus 1 hour for each additional 500,000 tests or portion thereof multiplied by a $35 hourly rate.		

[1] Average hourly rates and user fees are shown since individual contracts are negotiated with 53 State survey agencies. The actual user fee for determining compliance would depend upon the State in which the laboratory is located. The $35 hourly rate is based on total surveyor time, which includes the time surveyors are not involved in activities directly related to determinations of compliance. The unit cost budget methodology is based on actual surveyor time to conduct compliance evaluations, which is about $27 per hour. We add an adjustment of $8 per hour to cover surveyor costs for holidays, vacation, sick leave, and attendance at training courses. Therefore, the cost of these other work-related activities has been included in the user fee methodology.

[2] Includes evaluating qualifications of personnel; monitoring proficiency testing; conducting onsite surveys; developing deficiency statements; and evaluating laboratories plans to correct deficiencies.

(Note that this final rule contains a change concerning compliance inspections of State-exempt laboratories that is discussed, in section IV of this preamble, in response to comments on § 493.645. Also, note that this final rule adds a new category within Schedule A for those laboratories performing no more than 2,000 laboratory tests per year. The fee associated with determining compliance for this category during FY 1992 is $300.)

We proposed that, under the proposed methodology, the fee that a laboratory issued a certificate of accreditation would pay [1] in fiscal year 1991 to share the cost of the 5 percent random inspections discussed earlier would be:

Schedule A Laboratories	$42
Schedule B Laboratories	56
Schedule C Laboratories	70
Schedule D Laboratories	82
Schedule E Laboratories	95
Schedule F Laboratories	107
Schedule G Laboratories	119
Schedule H Laboratories	131
Schedule I Laboratories	144
Schedule J Laboratories	[1]

[1] Schedule I base fee plus $12 for each additional 500,000 tests or portion thereof.

(Note that this final rule contains a change concerning responsibility for the cost of compliance inspections of State-exempt laboratories that is discussed in section IV of this preamble in response to comments on § 493.645.

We proposed that, under the proposed methodology, the average fee that a laboratory issued a certificate of accreditation would pay, if it is necessary to perform the following activities in the case of that particular laboratory during fiscal year 1991, would be:

Follow-up visits or complaint investigations:

Schedule A Laboratories	$525
Schedule B Laboratories	595
Schedule C Laboratories	665
Schedule D Laboratories	735
Schedule E Laboratories	840

[1] Includes evaluating qualifications of personnel; monitoring proficiency testing; conducting onsite surveys; developing deficiency statements; and evaluating laboratories plans to correct deficiencies.

Schedule F Laboratories	910
Schedule G Laboratories	980
Schedule H Laboratories	1,050
Schedule I Laboratories	1,120
Schedule J Laboratories	(1)

[1] Schedule I base fee plus $70 for each additional 500,000 tests or portion thereof.

Sanctions/Hearing:

Schedule A Laboratories	$280
Schedule B Laboratories	315
Schedule C Laboratories	350
Schedule D Laboratories	385
Schedule E Laboratories	420
Schedule F Laboratories	455
Schedule G Laboratories	490
Schedule H Laboratories	525
Schedule I Laboratories	560
Schedule J Laboratories	(1)

[1] Schedule I base fee plus $35 for each additional 500,000 tests or portion thereof.

(Note that this final rule contains a change concerning the application of the above costs to State-exempt laboratories that is discussed in section IV of this preamble in response to comments on § 493.645.)

We proposed that the minimum fee that a laboratory would be required to pay for determination of program compliance would be the amount representing the biennial inspection costs in the aforementioned schedules. If the laboratory requires additonal survey time as a result of followup visit(s), certificate revisions, complaint investigation(s) that are substantiated, intermediate sanctions, appeals or hearings, an additional assessment will be made for such activities.

IV. Analysis of and Responses to Public Comments

We received 93 comments in response to the proposed rule published August 3, 1990. Commenters included professional organizations, hospitals, home health agencies, medical and professional organizations, and individuals. While many of the commenters raised general concerns about the proposed application procedures and fee schedule, their major concerns pertained to the proposed regulations published in the **Federal Register** on May 21, 1990 (55 FR 20896) that would establish CLIA health and safety requirements based on the complexity of testing performed. The issues raised by commenters concerning tests and procedures that will be eligible for waiver or exclusion are addressed in the final rule and complexity list published elsewhere in this edition of the **Federal Register**. We have based our fees on our best estimates of the costs necessary to implement and administer the CLIA program. Once better data are available on the actual costs necessary to operate the CLIA program, we will adjust the fee schedules, as appropriate.

General Comments

Comment; A few commenters recommended that HCFA republish or "repropose" the proposed rule for user fees or postpone publication of the final rule until the proposed certification standards published May 21, 1990 (HSQ–176–P) are established. The commenters indicated that without knowledge of the certification standards establishing the regulatory framework applicable to all facilities performing testing, they could not provide meaningful comments on the proposed regulations governing fee schedules.

Response: Based upon concerns of the commenters, we have decided to wait until publication of the final CLIA laboratory standards (HSQ–176–F) before we collect fees. We will collect fees based upon the volume and scope of testing that laboratories perform. No fees will be collected from laboratories that elect to discontinue laboratory testing before the effective date of HSQ–176–F.

Also, to minimize the overall impact of this regulation on the laboratory community, we have: (1) Restructured the fee schedule by establishing, in Schedule A, a separate fee ($300) for compliance inspections of low-volume laboratories that conduct 2,000 or fewer tests per year, and (2) revised the cost of issuing registration certificates and certificates from $261 across-the-board to $100, $350, or $600 depending on the scope and volume of laboratory testing.

Section 493.602 Scope and Section 493.606 Applicability

We received numerous inquiries questioning whether CLIA is applicable to laboratories that conduct testing only for forensic purposes. We have determined that CLIA does not apply to such entities provided that these entities do not conduct testing for "the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health, of human beings." This means that, generally, CLIA would not apply to law enforcement agencies that conduct such testing to determine whether there is a violation of the law. Specifically, the clear thrust of the CLIA legislative history is in seeing that medical diagnosis and treatment are based upon accurate and reliable laboratory test results, not that laboratory testing should be regulated outside the patient care context. However, if the entity conducts testing for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings, the entity would be subject to CLIA. The determining factor is not the test itself, but the purpose for which the test is conducted. We have revised proposed § 493.602 to clarify that the requirements of this rule apply to all laboratories "that test human specimens for health purposes."

Comment: One commenter suggested that it may be appropriate to conduct inspections of laboratories that are not under any regulatory agency but that hospitals that are accredited by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) should not be subject to CLIA.

Response: CLIA authorizes the recognitiion of accreditation and State programs that have standards equal to or more stringent than the CLIA requirements. On August 20, 1990, we published in the **Federal Register** (55 FR 33938) proposed criteria for recognition of accreditation and State licensure programs. Once the CLIA requirements are published in final, including the health and safety standards and criteria for recognition of accreditation and State licensure programs, accreditation programs and State licensure programs will be able to apply for recognition under CLIA. Those programs with standards equal to or more stringent than CLIA will be recognized. A laboratory accredited by an approved accreditation program will be deemed to meet the CLIA requirements provided the laboratory submits an application, meets the application requirements, and pays the appropriate fee for a certificate of accreditation. Laboratories with certificates of accreditation will be subject to random inspections to monitor the accreditation organization standards with respect to their equivalency with CLIA requirements.

Further, in response to comments received on the August 20, 1990 proposed rule concerning recognition of accreditation and State programs, we reexamined the statutory provisions regarding State licensing programs. Section 353(p)(2) of PHSA specifies that, if a State enacts laws that provide for requirements equal to or more stringent than the CLIA statutory requirements or requirements of the regulations, the Secretary may exempt clinical laboratories in that State from the CLIA requirements. We have chosen to exercise that authority and will exempt from the requirements of CLIA laboratories located in States whose licensure programs are approved by HHS. Such "State-exempt" laboratories will not require certification by HHS and will not be subject to fees. We have

revised proposed § 493.610, "Registration certificate or certificate required for laboratories," to reflect this change. We have also changed the title of the section to "Certificate requirements for laboratories" to more accurately reflect the content of this section. State-exempt laboratories will be required to permit Federal inspectors to conduct inspections to ensure standards are being enforced in an appropriate manner. We have revised proposed § 493.602 to add that this rule sets forth the methodology for determining the amount of the fees for Federal validation of State-exempt laboratories. Further, we have revised proposed § 493.645, which concerns additional fees, to add that HHS assesses the State the costs of the validation inspections and its proportionate share of the general overhead costs for the development and implementation of CLIA. We have made this revision because we realize that laboratories in these States are exempt from all CLIA requirements, including the statute's fee provisions. At the same time, because the Congress expects us to recover all Federal CLIA expenses through the collection of fees, we realized that the costs of validation inspections for a CLIA-exempt laboratory had to be reflected in our fee structure. Accordingly, we concluded that such costs ought to be recovered through the assessment of fees from those States seeking Federal approval of their licensure programs under section 353(p) of the PHSA. We view this agreement to pay such fees as a condition of our approval of such licensure programs. Whether States would in turn assess laboratories these fees is a matter that is behond the scope of CLIA '88.

Comment: One commenter sugggested that a laboratory that is enrolled in and acceptably participating in an independent or external commercial quality control program should be exempt from inspections and the fees for inspection. The commenter agreed that a fee for issuing certificates should be charged.

Response: With the exception of laboratories exempted by § 493.3 (published elsewhere in this issue of the **Federal Register**), every facility testing human specimens "for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings" is subject to CLIA. There is no provision in CLIA to exempt laboratories because they are enrolled and participate in a quality control program.

Comment: One commenter suggested that the fees paid for JCAHO accreditation and the inspection by the State for licensure should be accepted in total and in place of collecting any additional fees or conducting inspections under CLIA.

Response: Once CLIA is fully implemented, a laboratory that is accredited by an accreditation program that is approved by HHS will need to apply for a CLIA certificate of accreditation and pay the appropriate fee. All certificate fees include the Federal costs associated with establishing the CLIA requirements, conducting the studies mandated by CLIA, contractor-related costs, and costs for the implementation and operation of the CLIA program. In addition, HHS must recoup all costs associated with the monitoring of the approved private accrediting organization's performance in determining the laboratory's compliance with the CLIA requirements. CLIA requires that all certificate holders, including those which might have a certificate of accreditation, must share in the costs that the government incurs in administering the CLIA program.

A clinical laboratory located within a State that has had its licensing program approved by HHS (that is, a "State-exempt" laboratory) is not required to apply for a certificate. State-exempt laboratories are closely monitored by their State licensing program. However, like an accredited laboratory, a State-exempt laboratory may undergo a random survey to validate that the licensing program's standards and criteria continue to be applied appropriately. Unlike accredited laboratories, which must pay for their share of the costs of these sample validation surveys, State-exempt laboratories do not pay these costs to HHS. Rather, as stated above, HHS will asssess the State for all costs associated with these surveys.

Comment: A few commenters indicated that, in consideration of costs, we should perform random inspections of laboratories or target inspections of laboratories that have been responsible for providing inaccurate results. The commenters noted that inspecting all the laboratories in the country would increase medical costs.

Response: Consistent with section 353(g)(2) of the PHSA, once CLIA is fully implemented, we intend to conduct an inspection at least every 2 years of all laboratories issued a certificate. Laboratories with a certificate of accreditation or State-exempt laboratories are subject to random validation inspections. However, no routine inspections are required for certificate of wavier laboratories.

Comment: One commenter recommended that, with the expanded level system, there should be a role for self certification by means of the application for the lower laboratory levels. The commenter stated that HHS should retain the right to inspect for cause or as part of a random survey, but the commenter saw no need for HHS to inspect every laboratory location during the initiation phase of the regulation.

Response: Because the statute requires that the Secretary undertake inspections, we could not adopt the system of self-certification suggested by the commenter. After an initial certificate is issued, we intend to conduct at least biennial inspections.

Comment: Several commenters indicated that home health agencies (HHAs) and hospices should be exempt from the CLIA requirements because HHAs and hospices are not clinical laboratories since these facilities typically perform screening procedures only or provide instructions to patients for performing self-administered tests. The commenters stated that the fees and requirements imposed by these regulations would have devastating effects on the budgets of HHAs. They also stated that the fee requirements, even those for certificates of waiver, combined with threatened cuts in Medicare payments and State budgets for Medicaid, will force HHAs to stop offering these patient services and assisting patients in the performance of self-administered tests in the home.

Response: Section 353 of the PHSA applies to every facility testing human specimens "for the purpose of providing information for the diagnosis, prevention, or treatment of any disease of impairment of, or the assessment of the health of, human beings * * *." If an HHA or hospice performs testing for these purposes, we cannot exempt it from the CLIA requirements. On the other hand, we acknowledge that certain activities that involve testing are not within the range of concerns that the Congress had when it enacted CLIA. Specifically, we do not believe that the Congress had any wish to see us regulate, as laboratories, individuals who may be self-administering a test in their own home with an appliance that has been approved for that over-the-counter purpose by the Food and Drug Administration. Thus, to the extent that an HHA or hospice that is providing care in an individual's home is engaged solely in assisting an individual in performing a test, which if performed by

the individual would be beyond CLIA's reach, we have no intent to impose a CLIA fee on the HHA or hospice by virtue of that activity. If the HHA or hospice engages in testing outside this narrow context, however, section 353 of the PHSA also requires "payment of fees for the issuance and renewal of certificates, except that the Secretary shall only require a nominal fee for the issuance and renewal of certificates of waiver." After publication of the final CLIA standards regulation (HSQ–176–F), laboratories will be required to meet CLIA application requirements and pay the established fee for a certificate of waiver or registration certificate. The bases for the fee amounts are discussed in our responses to comments under § 493.638, "Registration certificate and certificate fees," and § 493.646, "Payment of fees."

Comment: One commenter (representing an HHA) questioned whether we expect individual HHA patients to apply for CLIA certification since they own reflectance meters and conduct blood glucose testing on themselves. Initially, HHA staff provides training to the patients to assist them in performing tests on themselves after discharge from the HHA.

Response: We will not require individual patients to apply for CLIA certification. CLIA only applies to "facilities" performing laboratory testing on human specimens. Therefore, except for those laboratories listed in § 493.3 (published elsewhere in this issue of the **Federal Register**) that are excluded from CLIA, facilities that test human specimens must apply for a registration certificate. In HSQ–176–F, we will establish regulations that are based on complexity of testing and specify which tests meet the requirements for waiver. In addition, as previously explained, to the extent that an HHA or hospice that is providing care in an individual's home is engaged solely in assisting an individual in performing a test, which if performed by the individual would be beyond CLIA's reach, we have no intent to impose a CLIA fee on the hospice by virtue of that activity.

Comment: Another commenter (representing an HHA/hospice) indicated that registered nurses on occasion perform finger sticks and/or venapunctures as a courtesy to a patient, family member, or physician. The commenter questioned whether, since the related examinations are not conducted in the hospice or HHA office, the certification would be issued to the patient's home, the nurse's automobile, or the office. The commenter also asked whether the HHA/hospice would be identified as a laboratory if staff perform an occasional waived test as a courtesy to the patient or physician.

Response: In situations in which a hospice or HHA conducts testing at a temporary location or patients home, the hospice or HHA is subject to the requirements of CLIA. However, the certificate would be issued to the HHA or hospice office or branch location not to the temporary location of the patient's home or the nurse's automobile unless the automobile is a mobile vehicle that patients come to for testing. Since waived tests are encompassed by the CLIA statute, an HHA or hospice staff that performs such a test for the convenience of the patient would automatically subject the HHA or hospice to CLIA's requirements. In addition, as previously explained, to the extent that an HHA or hospice that is providing care in an individual's home is engaged solely in assisting an individual in performing a test, which if performed by the individual would be beyond CLIA's reach, we have no intent to impose a CLIA fee on the HHA or hospice by virtue of that activity.

Comment: A commenter, representing a State Home Care Association, recommended that the definition of location not be construed to include home health care clinics held at a variety of sites throughout a county or at individual homes. They advocated the location being defined as the office location of the agency or the area of service for home health agencies.

Response: Facilities that provide services at temporary sites such as patients' homes or shopping centers do not have to obtain certificates for these locations, but the home base must apply.

Comment: One commenter recommended that the proposed fee schedules be reexamined to consider the burden and cost imposed on rural facilities. The commenter noted that public health departments and small rural hospitals will not be able to effectively accommodate these uncertain costs in their financially strapped budgets.

Response: In a change from our proposed rule and in an attempt to fairly distribute the cost of this program, we are reducing the fees for registration certificate purposes. Largely to benefit laboratories such as those found in small rural hospitals, we have established a range of fees that is based on the scope and volume of laboratory testing. We have also reduced the compliance fee for low-volume laboratories that conduct 2,000 or fewer tests per year. As better data become available on the cost necessary to operate the CLIA program, we will revise the fees.

Comment: Several commenters expressed concern about the effect of CLIA certification on the Women, Infants and Children (WIC) program. They stated that the financial burden for obtaining a certificate for the limited number of tests performed (primarily hemoglobin/hematocrit) will increase the administrative cost and limit the ability of these programs to provide patient services.

Response: WIC programs are subject to CLIA because they test human specimens for health purposes. We have revised the regulation to permit laboratories that do limited testing and are directed by not-for-profit or Federal, State, or local government organizations to operate under one certificate.

Comment: One commenter expressed concern that the fee schedule is unfavorably skewed against his facility because his laboratory performs a very large volume of a limited number of test types.

Response: Our fee schedules reflect our best estimates of current cost information associated with completing the inspection process. The greater a laboratory's test volume, the more time it will take (and the higher the cost will be) to properly evaluate whether the laboratory is conducting tests in compliance with Federal requirements. As more definitive data becomes available, we intend to adjust the fee schedules, as appropriate.

Comment: One commenter questioned how we will determine the affected entities and adequately enforce the CLIA provisions, since we had stated in the proposed rule that "currently we are unable to determine with any high degree of accuracy, due to lack of data, the universe of laboratories that would be compelled to meet the requirements of these provisions."

Response: As we outlined under section II.B. of this preamble, we will use various approaches to identify all entities that test human specimens and are not excluded from CLIA and notify them of the CLIA requirements and necessity of being certified under CLIA. However, the law places the burden on the laboratory to come forward and obtain a certificate if it is to test specimens. Unless the laboratory is State-exempt, operation of a laboratory without a certificate is a violation of the law and will subject the laboratory to the penalties outlined in the law.

Comment: Several commenters indicated that physicians who perform laboratory tests for their patients view

these laboratory tests as an integral component of their practice, not as a function of a separate, distinct facility or a "laboratory" in the common meaning, and, therefore, should be exempt from CLIA requirements. One commenter also indicated that we have not defined what constitutes a "laboratory" in either this rule or the proposed rule published May 21, 1990 and that has created problems in estimating the number of entities regulated under CLIA.

Response: Congress fully intended that CLIA apply to physician offices that perform testing services for patients, as reflected in the Report from the Committee on Energy and Commerce that accompanied the CLIA legislation (H.R. Rep. No. 5150, 100th Cong., 2nd Sess. pages 27–39 (1988)). For example, when discussing standards, the Report specifically states at section 101(f) that "* * * two laboratories otherwise identical, would be subject to the same standards and requirements, notwithstanding that one is located in a physician's office and the other in a different setting." Additionally in section 102, with respect to effective dates, the Report states that "* * * the number of laboratories subject to Federal certification for the first time on January 1, 1990 may exceed 100,000. Moreover, many of these will be physician office laboratories performing a limited range of testing."

Section 493.610 Registration Certificate or Certificate Required for Laboratories (Now Titled "Certificate Requirements for Laboratories")

Comments that affect § 493.610 are reflected in other sections of this preamble.

Section 493.614 Application Procedures

Comment: Some commenters believed that it is the government's responsibility to inform all laboratories of what actions are necessary to comply with the law (CLIA).

Response: We have sent a questionnaire to all laboratories approved for participation in the Medicare or Medicaid program or authorized to test specimens in interstate commerce, as well as any other laboratories we were able to identify that we believe may be subject to the provisions of CLIA. However, the law clearly places the burden on the laboratory to secure the needed certification to operate as a laboratory. Once the standards regulation, HSQ–176–F, is published, we will bill laboratories based on test volume.

Comment: Many commenters indicated that the application requirements for certification are burdensome due to the data required and time involved for the staff to collect the information. Laboratories indicated that the paperwork involved in completing the initial application as well as maintaining the ongoing statistics for renewal application will increase the laboratory's operational expenses.

Response: As stated above, we sent a questionnaire to entities we were able to identify as performing laboratory testing. After the standards rule, HSQ–176–F, is published, we will send applications and bills to laboratories subject to CLIA. We will attempt to reduce the burden of these forms as much as possible; however, certain information is required by the statute.

Comment: One commenter indicated that the application requirements would be particularly burdensome for hospitals that have multiple laboratory locations (that is, a hospital with a critical care unit, operating rooms, surgery center, dialysis unit, etc.).

Response: The application requirements are those required by section 353(d)(1)(A) of the PHSA. In consideration of the organizational and operational aspects of hospitals, we will allow laboratories within a hospital that are under common direction and located at the same street address to apply for a single certification or multiple certificates. Therefore, a hospital could apply for a single certificate to cover all testing sites at the same address, or, at its option, apply for separate certificates for each department of service; for example, a critical care unit, operating rooms, surgery centers, dialysis units. In addition, an organization that does limited testing (that is, few types of tests) for screening or treatment of individuals that is directed by a not-for-profit or Federal, State, or local government organization can operate (at its option) under one certificate; for example, the WIC program. We have revised proposed § 493.614 to include these options.

Comment: One commenter indicated that the proposed application process seems time consuming and costly. The commenter suggested that we carefully consider each laboratory's current operation, particularly those facilities that are already licensed by the State or approved by an accrediting organization.

Response: Section 353(b) of the PHSA requires that "No person may solicit or accept materials derived from the human body for laboratory examination or other procedure unless there is in effect for the laboratory a certificate issued by the Secretary * * *." The statute requires as well that, in order for a laboratory to receive a certificate, it must comply with the statute's application requirements. This includes laboratories accredited by an accrediting organization. As stated previously, we are exercising the authority contained in section 353(p) of PHSA to exempt from CLIA requirements laboratories licensed by an approved State licensure program. Those laboratories will not be required to have a certificate.

Comment: One commenter expressed concern that CLIA does not take into consideration the impact that the application process would have on home health and community based agencies.

Response: CLIA provides no exclusion for HHAs. All facilities testing human specimens "for the purpose of providing information for diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings" are required to conform to CLIA. However, to the extent that an HHA or hospice that is providing care in an individual's home is engaged solely in assisting an individual in performing a test, which if performed by the individual would be beyond CLIA's reach, we have no intent to impose a CLIA fee on the HHA or hospice by virtue of that activity. In addition, since we will not begin the application or billing process until HSQ–176–F is published, an entity will be in a better position at that time to determine whether it wishes to continue laboratory testing.

Comment: One commenter stated that methodologies are often instrument-dependent for chemistry and immunochemistry testing and expressed the concern that laboratories would be unable to include the upgrade of equipment until a new application for certification was filed and acted upon. The commenter also questioned whether a laboratory would be in violation of CLIA if it began using a kit or methodology not on its certificate application. Another commenter indicated that if notification to HHS is required before modifications can be made to the test menu, the efficient and effective operation of the laboratory will be severely inhibited. The commenter recommended that laboratories adding tests that would be included in the service levels specified on the certificate should not be charged an additional fee or need to notify HHS before performing the test. Additions to, deletions from, and changes in the list of tests for which the laboratory has been issued a certificate could be communicated to

HHS every 2 years, at the time of biennial inspection.

Response: The CLIA statute requires that we collect information on the methodologies for the test procedures performed. Registration certificates will not specify the specialties/subspecialties of services offered, except as indicated in § 493.633. Thus, laboratories will be able to notify us of the revised services offered and are not required to obtain an amended registration certificate. With respect to certificates and certificates of accreditation, we plan to list categories or specialties or subspecialties of testing on the certificate. (Except that certificates of waiver will only reflect testing in the waived category.) We will not routinely list individual test procedures. Therefore, laboratories will not be required to obtain a revised certificate provided the test additions are covered in the specialties or subspecialties of services listed on the certificate. CLIA requires laboratories that are issued a regular certificate or certificate of accreditation to report changes in tests not later than 6 months after the change has been put in effect as indicated in § 493.633. However, if a laboratory with a certificate of waiver expands its services beyond the waived tests, it must notify HHS before performing such testing. In such instances, a registration certificate will be issued to the laboratory so that the additional testing can be performed until we determine compliance with Federal requirements and issue a regular certificate.

Comment: One organization supports the intent of CLIA to strengthen quality control and quality assurance activities in the performance of laboratory tests. However, the commenter is concerned that burdensome application processes and excessive fees may cause a significant reduction in laboratory services provided in physician offices. The commenter indicated that this may result in a potentially large gap in access to laboratory services for patients everywhere, but most critically for those in rural areas and other sites where alternative testing sites are scarce.

Response: As stated earlier, the application and fee collection requirements are specified in the law. The fee schedules are based on our best estimates of the Federal costs associated with the development and administration of CLIA regulations, reviewing applications and collecting fees, Federally mandated studies, contractor costs, and evaluating laboratories for determination of compliance. As better data become available on the cost necessary to operate the CLIA program, we intend to seek input from the public and will adjust the fee schedules as appropriate. In addition, we have reduced the compliance fee for small laboratories conducting not more than 2,000 tests per year and have also lowered the certificate fee for small laboratories to $100 from the proposed $261 level. These very small laboratories are the type often found in low volume, rural clinics or small doctors" offices.

Section 493.614 Responses to Request for Comments

In the preamble of the proposed rule we specifically requested suggestions on ways the reporting burden required for certificate application can be minimized, while meeting the legislative intent. We received the following responses to this request.

Comment: Many commenters urged that the application include a pre-printed "checklist." One commenter recommended that we develop special forms to update certifications that would require information only on the "changes" that occurred since the initial application. Another commenter suggested that separate applications be developed and utilized for waiver, Level I, and Level II laboratories, with the information requested targeted to the requirements for each type of certificate.

Response: We will take into account any measure that is feasible to simplify the application process. When CLIA is fully implemented, we plan to have application forms that are simple, easy to complete, and appropriate for all categories of laboratory testing. Until that time we will use a questionnaire that will collect the basic information necessary to identify laboratories subject to CLIA.

Comment: One commenter urged HHS to consider revising the fee schedule to discount multiple certificates issued to a single institution and to reduce reporting burden by allowing hospitals to file a single application that would encompass all the certificates to be issued to its laboratories.

Response: A certificate may be issued to a hospital location identified by a specific street address to cover multiple testing sites within the hospital provided the different testing sites are under common directorship. Likewise the hospital may wish to have multiple certificates for different testing sites in the same location. We believe the fee schedule is established appropriately to represent general CLIA implementation and operational costs as well as the costs for determining compliance that correlate with the volume and scope of services performed. Additionally, organizations that do limited testing (that is, few types of tests) for screening or treatment of individuals that are directed by not-for-profit or Federal, State, or local government organizations can operate (at their option) under one certificate, for example, the WIC program.

Comment: One commenter expressed concern that the fee regulations as proposed did not consider the testing situations of public health agencies. These agencies traditionally provide services for underserved populations and for the prevention and control of communicable diseases. Even though the laboratory testing may be simple and the testing volume may be low, in order to be effective, those agencies must provide services that are convenient to the populations served. The application procedures and fee schedules proposed would be a tremendous burden to public health agencies.

Response: CLIA is specific that "No person may solicit or accept materials derived from the human body for laboratory examination or other procedure unless there is in effect for the laboratory a certificate issued by the Secretary * * *." For a laboratory that is not at a fixed location, that is, a "laboratory" that moves from testing site to testing site such as a health screening fair or other temporary testing location, we would issue a certificate to the home base. If the laboratory has a certificate, other than a certificate of waiver, we would conduct routine inspections at selected testing sites or locations.

Comment: One commenter noted that the proposed rule states that the certificate application requirements are based on section 353(d)(1)(A) of the PHSA, which requires laboratories to describe "characteristics," "number and types," and "methodologies" of the tests proposed to be performed. Individual test names are not required by the statute. Therefore, the commenter recommended that the application not require specific names, but rather list groups of procedures, such groups being defined by their characteristics, types, and methodologies. Then, as long as a laboratory has included a group of procedures on its application, it may add any additional procedure within that group without notifying HHS or paying an additional fee.

Response: Except as exempt by § 493.3 (published elsewhere in this issue of the **Federal Register**), all laboratories must obtain a registration certificate or certificate of waiver. An

inspection will not be required for issuance of a registration certificate. Once CLIA is fully implemented, we must know the "types" of tests or names of tests that a laboratory performs to determine whether a laboratory may be issued a certificate of waiver. Additionally, test names are needed to correlate with methodologies performed and to categorize the procedures or examinations by specialty or subspecialty of service for issuance of a regular certificate. CLIA requires that each laboratory have a certificate applicable to the specialty or subspecialty of service to cover the categories of examinations or procedures performed by the laboratory unless it is granted an exemption as a laboratory licensed by an approved State licensure program. The certificate will not include test names but instead specialties or subspecialties of services. As long as the laboratory has a valid certificate to cover the specialties or subspecialties of services performed, the laboratory may add or delete tests or examinations without revising the CLIA certificate. (Certificates of waiver will only reflect testing in the waived category.) As indicated in § 493.633, a laboratory with a certificate of waiver must notify HHS before performing tests not listed in the waiver test category, while a laboratory with a certificate must notify HHS or a laboratory with a certificate of accreditation must notify the accrediting organization within 6 months of any change in testing.

Comment: In order to minimize the reporting burden, one commenter recommended that laboratories be allowed to indicate on the application form that there are several methodologies that they could potentially use to perform a particular test without regard to the methodology most commonly used. The commenter suggested that a list of the methodologies most commonly performed could be attached to the application. In this regard, another commenter asked whether, if several alternative methods for performing a particular analysis or examination were listed on the application, the laboratory would be required to stock all the reagents and perform proficiency surveys using all methodologies listed. One commenter indicated that the use of pre-printed forms listing methodologies and tests could be restrictive and would rapidly become outdated.

Response: CLIA legislation and application procedures require laboratories to include as part of the application "the methodologies for laboratory examinations and other procedures employed." Therefore, the laboratory must include only those methodologies actually used for testing. Test reagents should be available to perform the methodologies listed. Laboratories will be required to perform proficiency testing surveys as required under CLIA standards regulation HSQ–176–F, which is published as a separate rule in this edition of the Federal Register. We recognize that pre-printed forms could rapidly become outdated, and we will consider this factor in designing the forms.

Comment: A number of commenters indicated support of the use of pre-printed application forms. One commenter suggested that pre-printed application forms be used to collect information on the education, training, and experience of each employee rather than requiring employee résumés. One commenter recommended that the form not require a detailed description of the qualifications of each laboratory employee but rather a printed statement that all personnel comply with CLIA requirements. The commenter said this statement could be signed and attested to by the individual representing the facility who signs the application form. Another commenter pointed out, however, that the use of pre-printed forms for the certification of technical personnel would be restrictive and would not allow for the continual updating of educational status.

Response: As stated above, we recognize that pre-printed forms could rapidly become outdated and will consider this factor in designing the forms. However, CLIA requires that we obtain information concerning "the qualifications (educational background, training and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and other procedures * * *." We all strive to develop application forms that require the least burden possible to complete.

Comment: Several commenters expressed concern with respect to the requirement that a separate application be filed for each laboratory location. One commenter recommended that the institution be allowed to determine the number of applications for that institution based on who has control or jurisdiction over the testing site within the institution. The institution could elect to be "certified as a whole" (that is, one certificate) or have multiple sites with separate certificates. Another commenter recommended that there should only be one application and fee required if the same supervising personnel are working in multiple test sites within one corporation.

Response: As stated earlier, we will provide flexibility to a hospital located at one street address and under common direction to allow it to determine the number of certificates required. However, if the hospital conducts testing at separate locations, (that is, different street addresses) each location must be evaluated for determination of compliance with CLIA. Laboratories that do limited testing (that is, few types of tests) for screening or treatment of individuals that are directed by not-for-profit or Federal, State, or local government organizations can operate (at their option) under one certificate; for example, the WIC program.

Comment: One commenter requested clarification on whether separate waiver certificates would be required for one-time sites, such as health fairs.

Response: A separate certificate will be required for each permanent testing location, as discussed in § 493.614(b); however, health fairs that move to temporary sites to provide services will not be required to have a certificate or certificate of waiver at each temporary location. Once CLIA is fully implemented, if the temporary sites perform only waived tests, we will issue a certificate of waiver to the home base location. For laboratories not qualifying for a certificate of waiver, we will issue the certificate to the home base and evaluate compliance, on occasion, at one or more temporary locations.

Comment: One commenter indicated that there would be an increase in administrative costs for an agency to complete each application. In the event that the WIC program is covered by final CLIA regulations, the commenter recommended that special, simpler application forms be developed for use by WIC programs to reduce the time and costs involved and eliminate irrelevant paperwork.

Response: We will make every effort to simplify application forms for all laboratories, including WIC program laboratories, to ensure that only minimum effort consistent with statutory requirements is necessary to complete the forms.

Comment: One commenter indicated that the requirement for collecting annual test volumes as part of the application for certification was not relevant to proficiency testing since it should be the same whether one or multiple tests are performed. The commenter also recommended that the updating of a certificate should be as simple as possible.

Response: As stated earlier, CLIA application requirements specify that HHS collect information on "the number and types of laboratory examinations and other procedures performed." This information collection requirement is not related to proficiency testing. As previously indicated, we will make every effort to simplify the application forms, which will include the procedures for updating information.

Comment: One commenter recommended that the application be correlated with test complexity as proposed in a separate CLIA rule. The commenter suggested that we permit applicants to determine the level of testing based on testing performed and that, in all cases, the forms should be generic enough to not impede the use of new technology. The commenter also indicated that the term laboratory "location" should be changed to laboratory "practice" since this change would allow a reduction in paperwork and preserve the ability of mobile "screeners" to conduct their services.

Response: We will allow mobile laboratories to obtain a single certificate for each mobile testing facility (or van) that will reflect the home base address for each testing entity that furnishes services. A mobile laboratory is a permanent unit that is comprised of all equipment and supplies necessary to provide or perform services in the van or conveyance that travels to the patient(s) to furnish services. Laboratories that transport equipment and supplies to a patient's home, a shopping center, or between temporary locations in which the testing is performed at the temporary location will be issued a single certificate for the home base to cover testing at each temporary location. We have revised proposed § 493.614 to clarify that laboratories within a hospital can be covered by a single certificate to allow testing at a number of temporary locations.

Comment: One commenter indicated that since tests on the waived list are not subject to personnel requirements, entities applying for a certificate of waiver should not be required to report this information. Similarly, the applicants should not be required to disclose the methodologies used for waived tests, as these methodologies have already been waived as well. The commenter also stated that, since certificate of waiver laboratories are not subject to proficiency testing, they should not be required to furnish data on the total number of tests performed annually.

Response: The application requirements specified are required by law regardless of whether the laboratory is issued a regular certificate, certificate of waiver, or certificate of accreditation. Note that certificate of waiver laboratories are not required to report changes in supervisor.

Comment: One commenter recommended that HHS send, if time permits, application forms to a sample of laboratories to ensure that the forms solicit the necessary information in the most appropriate manner.

Response: The application forms will be based on the application requirements of the statute. We will use the experience gained from the questionnaire issued as part of the implementation process of this rule to develop the application forms to be used after CLIA is fully implemented.

Section 493.618 Additional Application Requirements

Comment: One commenter (a State Health Department) indicated that the proposed rule was unclear as to when onsite visits are required and what they will cost. The commenter indicated that § 493.618 does not state which laboratories will require onsite visits.

Response: Section 493.618 sets forth application requirements and is not the appropriate place to include the detailed requirements related to inspections. Inspection requirements were specified in the proposed rule HSQ–176–P published on May 21, 1990. However, as we explained in this preamble, all laboratories will be issued registration certificates or certificates of waiver initially. Laboratories will not be subject to routine inspections for compliance with health and safety standards under CLIA until those standards are established. However, laboratories that are currently approved to participate in the Medicare or Medicaid program or authorized to test specimens in interstate commerce remain subject to the current Federal standards for laboratories at 42 CFR part 493. In addition, all laboratories (including those issued registration certificates) are subject to inspections as the result of complaints or other problems related to noncompliance with CLIA statutory requirements.

Once the CLIA health and safety standards contained in HSQ–176–F are effective, all laboratories not issued a certificate of waiver will be subject to onsite inspections on a biennial basis. A laboratory issued a certificate of waiver will not be subject to these "routine" inspections; however, the Secretary has the authority to evaluate complaints and verify the tests being performed by the laboratory. Laboratories that qualify for a certificate of accreditation will be subject to routine inspections by the accreditation programs, as well as validation surveys on a random basis to verify accreditation program equivalency, and surveys to investigate complaints that allege regulatory noncompliance. Licensed laboratories located in a State whose licensure program is approved by HHS are exempt from CLIA (that is, State-exempt) but would be subject to Federal inspections on a random basis to verify that standards are being enforced in a manner comparable to those applied under CLIA.

Comment: One commenter indicated that the proposed rule requires all laboratories, except those issued a certificate of waiver, to agree to routine inspections and this contradicted the proposed rule published May 21, 1990 (HSQ–176–P). The commenter indicated that in HSQ–176–P, at 55 FR 20903, we proposed unannounced inspections of certificate of waiver laboratories even though these laboratories are exempt from routine inspections under 42 U.S.C. 263a(d)(2)(C) of CLIA. The commenter suggested that HHS take the position that certificate of waiver laboratories would not be subject to routine inspections, since this is consistent with the statute, and that we address the discrepancy between the two proposed rules.

Response: The language in both rules is correct. While certificate of waiver laboratories will not be subject to "routine" scheduled inspections (that is, every 2 years), the Secretary reserves the right to inspect a laboratory's operations if there is cause to question whether the laboratory is operating in a lawful and safe manner. In the preamble to the May 21, 1990 rule, we explained that "certificate of waiver laboratories, while exempted from routine inspections under section 353(d)(2)(C) of the PHS Act, are nevertheless subject to extraordinary inspections in certain instances through our enforcement authority contained in section 353(i) of the PHS Act." This section reserves the Secretary's right to make reasonable requests to conduct an unannounced inspection of a laboratory's operation if there is cause to question whether the laboratory is operating in a lawful and safe manner. While subsection (i) speaks to certificates, it is clear from sections 353 (b) and (c) of the PHSA that this term encompasses certificates of waiver as well. Such inspections would not be "routine." Since there is no conflict, no change has been made to the regulation.

Section 493.622 Appeals Procedures ["Opportunity for hearing" in proposed rule]

Comment: Several commenters expressed concern that the proposed rule would prohibit laboratories seeking initial certification from conducting business if their certification is denied or limited, unless the denial is overturned on appeal. They indicated that this could create a substantial hardship and that laboratories should not be penalized for a possible HHS error or the need to supply additional information. One commenter indicated that we should include provision for a reconsidered determination while another suggested that a "show cause" hearing be held before such action so that the laboratory can either correct problems before such a hearing or contest the denial of the initial certification. This commenter also suggested that a cost-benefit analysis be developed to determine whether some type of hearing should be afforded a person or entity denied an initial certificate.

Response: Registration certificates or certificates of waiver will be issued to all laboratories that meet application procedures prescribed by law and regulations and that pay the appropriate fee. Any laboratory that fails to comply with the application procedures will be notified of the requirements not met and be given an opportunity to achieve compliance. For example, if a laboratory failed to supply information concerning test methodologies, we would contact the laboratory and provide an opportunity for the submission of this information. In addition to providing laboratories an opportunity for an appeal in part 493, the proposed rule concerning enforcement procedures for laboratories (HSQ–179–P) published in the **Federal Register** on April 2, 1991 provides reconsideration of actions that are initial determinations. Any laboratory dissatisfied with HHS's denial of its application for a CLIA certificate or denial of approval to receive Medicare payment for its services or with HHS's refusal to convert the laboratory's registration certificate to a CLIA certificate may request a reconsideration in accordance with § 493.622. Section 493.622, as proposed in HSQ–177–P, specified that, in the above circumstances, the laboratory is provided an opportunity for "a hearing" in accordance with procedures set forth in part 498. We are revising proposed § 493.622 by changing the section heading to "Appeals procedures" and, in paragraph (a), substituting the words "an appeal" for the words "a hearing." These changes clarify that the laboratory has access to the full appeals process provided to it by part 498.

Since reconsideration of initial determinations are authorized, we do not believe that a cost-benefit analysis is necessary.

Comment: One commenter indicated that, in order to avoid financial hardships, either Medicare payments should continue until a hearing decision is issued or the hearing should be scheduled within 2 weeks of the finding of noncompliance.

Response: We disagree with the comment. Laboratories that are not in compliance with Federal requirements cannot be approved or maintain their approval for participation in Medicare unless they correct deficiencies within prescribed timeframes. Payments under Medicare may not be made to laboratories that are not approved for participation. Historically, it has always been the case that providers and suppliers in the Medicare program have no entitlement to a prior hearing once the agency has determined that deficiencies exist that prompt termination or approval cancellation—a position long upheld by the courts. Moreover, continuation of Medicare payments until a hearing decision would be contrary to the directive of the statute (section 6141 of Pub. L. 101–239) which requires all laboratories that participate in Medicare to meet the CLIA requirements. The purpose of this provision is to encourage compliance with the CLIA requirements.

With respect to requiring specific timeframes for scheduling hearings, we are unable to establish such timeframes due to unpredictability of the workload that may be generated by CLIA as well as other hearing obligations that the Department routinely incurs. The proposed rule on enforcement procedures for laboratories (HSQ–179–P) published in the **Federal Register** on April 2, 1991 elaborates on the effect on noncompliance with the CLIA requirements with respect to Medicare payment.

Comment: Another commenter indicated that we should elaborate on the appeals method, addressing time parameters, basis of cases, and who will rule on the denials.

Response: These issues are addressed in detail in the proposed rule on enforcement procedures for laboratories (HSQ–179–P) published in the **Federal Register** on April 2, 1991 and the final rule published elsewhere in this edition of the **Federal Register**. HSQ–179–F sets forth the rules for sanctions that HHS may impose on laboratories that are found not to meet Federal requirements.

Section 493.626 Registration Certificate

Note: As stated earlier, we have substituted, in this final rule, the term "registration certificate(s)" for the term "provisional certificate(s)." We have made this substitution even when discussing a comment.

Comment: One commenter indicated that the proposed rule was unclear as to whether laboratories would have to apply and pay twice; once for the registration certificate and again for the certificate. Another commenter sought clarification concerning the requirement for registration certificates and whether all new laboratories would be issued a registration certificate. They also questioned whether fees would be prorated if, for example, a full certificate was issued before the expiration of the registration certificate.

Response: Separate payments are required for the issuance of a registration certificate or certificate of waiver and, unless a laboratory is State-exempt, for any subsequent issuance of a "regular" certificate, certificate of waiver, or certificate of accreditation. The issuance of the registration certificate will allow time for HHS or its designee to determine compliance with the CLIA standards or for the laboratory to become accredited by an approved accreditation program or for approval of the State licensure program to exempt the laboratory from CLIA requirements.

Laboratories will not be expected to apply for their certificates. Rather, laboratories will be billed for certificates after successful completion of their on site compliance determination inspections.

In addition, as indicated in § 493.633(a)(2), a registration certificate will be issued to a laboratory that has a certificate of waiver and wishes to perform any examination or procedure not listed in the waived test category. To clarify this issue, we have revised proposed § 493.626 by adding that, except for a registration certificate issued to cover initial testing areas after a certificate has been issued as indicated in § 493.633(a)(2), the registration certificate will not include specialties/subspecialties of service, but will authorize the entity to conduct laboratory testing until a determination of the appropriate level of compliance can be made. Before expiration of the registration certificate, HHS will notify the laboratory of the fee amount for issuing the certificate and, if applicable, the amount of the fee for determination of compliance. The fees will not be

prorated since they are based on the Federal and State costs associated with the implementation and administration of CLIA and the cost involved in processing the applications and issuing certificates.

Comment: One commenter questioned the requirements in § 493.805 of the proposed rule to implement the CLIA health and safety requirements (HSQ–176–P) published May 21, 1990 that would require laboratories performing Level I or Level II tests to demonstrate satisfactory performance in one proficiency testing event of an approved proficiency testing program before issuance of a registration certificate. The commenter was concerned that there might not be any "approved" proficiency testing programs before the issuance of registration certificates.

Response: Laboratories are not required to achieve satisfactory performance in any proficiency testing event before issuance of a registration certificate. We proposed this requirement in HSQ–176–P as a mechanism to evaluate laboratory performance before authorizing "provisional" certification. HSQ–176 will have effective dates that ensure approval of proficiency testing programs before any laboratory would be penalized for non-participation. Moreover, the proposed requirements for HSQ–176 are being modified in the final rule published elsewhere in this edition of the **Federal Register**. However, Medicare, Medicaid, and interstate laboratories currently subject to the provisions of part 493 are subject to proficiency testing requirements at § 493.805.

Comment: One commenter expressed concern that proficiency testing might not be available to all laboratories for many reasons, including volume of customers to be serviced. The commenter indicated that HHS should provide for such situations by offering alternatives such as "in the event that the proficiency testing program is not able to administer the initial proficiency testing event required for provisional certification, the laboratory may be allowed to provide alternative evidence of satisfactory performance such as a manufacturer's proficiency testing program, or split sample testing."

Response: As indicated in the previous response, laboratories will not be required to participate in proficiency testing before issuance of a registration certificate. We understand proficiency testing program providers may have difficulty in accommodating the large number of applicant laboratories seeking enrollment. We will establish policies and procedures in HSQ–176–F to respond to this problem.

Section 493.631 Certificate of Waiver

Comment: Many commenters indicated that there should be no fee assessed for issuing a certificate of waiver, or that this fee should include only processing costs. One commenter also indicated that surveys for compliance would not be calculated into the waiver fees.

Response: Under CLIA, all certificate fees collected must be sufficient to cover the general costs of establishing the requirements to implement CLIA, including determining tests eligible for waiver. In addition to these general costs, the certificate of waiver fee includes the cost of issuing the certificate of waiver, the collection of the fees, and analysis of applications to determine if a laboratory should be issued a certificate of waiver. It also includes a share of the cost of random inspections to gather information for PHS evaluation of waiver test performance. In fact, the statute requires that we assess a "nominal fee" for the certificate of waiver. The fee we have set for a certificate of waiver is the lowest of any CLIA fees, and it is nominal.

Section 493.632 Certificate of Accreditation

Comment: One commenter noted that regulations concerning the programs acceptable for accreditation were not published, while other commenters recommended utilizing knowledge and experience of other inspecting agencies and focusing the HHS inspections on unlicensed unaccredited laboratories.

Response: As we indicated in the preamble of the proposed rule, a separate proposed rule contains the criteria for approving accreditation and State programs. That proposed rule (HSQ–181–P) was published August 20, 1990 (55 FR 33936) and sets forth the criteria we would use to evaluate and approve State programs and private non-profit organizations as accreditation programs. We are in the process of evaluating the comments received on that rule, and we will respond to them in the preamble of the final rule. However, based upon comments received on HSQ–181–P and upon further review of the statute, we are exempting from CLIA requirements laboratories licensed by and located in a State whose licensure program is approved by HHS. These State-exempt laboratories will not be required to have a certificate or pay fees. However, such laboratories are subject to random Federal inspections to validate that the State licensing program is applying standards at least equal to the CLIA standards. HHS will assess the State the costs of these inspections. We have revised proposed §§ 493.610, which concerns additional fees, and 493.645, which requires laboratory certification, to reflect this change.

Section 493.633 Applicability of the Certificate, Certificate of Waiver, and Certificate of Accreditation

Comment: Several commenters expressed concern about the proposed requirement that would prohibit a facility from performing a new test not included on the laboratory's certificate. Commenters indicated that requiring a laboratory to apply for and obtain a revised certificate before adding a test not listed on the certificate would have a negative impact on the laboratory's ability to furnish new test services in a timely manner. Commenters recommended that laboratories be permitted to notify us of the change and be permitted to perform the new test(s) on a provisional basis if the test(s) are within a previously certified specialty.

Response: Under this rule, registration certificates generally will not specify categories of testing performed. With respect to regular certificates, the certificate will not include test names but rather the specialties/subspecialties of services offered. Laboratories will not be required to obtain a revised certificate provided the test additions are covered in the categories of testing or specialties or subspecialties of service listed on the certificate. Changes in certificates will be necessary if there is a change in the categories of tests or specialties or subspecialties. A laboratory with a certificate must notify HHS within 6 months of any changes in tests or examinations performed. If the added testing is not in a specialty or subspecialty on its certificate, HHS may conduct (depending on the type and timing of the changes) a survey to determine compliance. A laboratory will be charged for survey costs only the cost incurred in evaluating the additional test. If compliance is determined, and upon payment of the revised certificate fee, a revised certificate will be issued that includes the additional specialties or subspecialties. A laboratory with a certificate of accreditation must notify the accreditation organization within 6 months of changes in its testing, and, when compliance is verified, a revised certificate of accreditation will be issued. We have revised proposed § 493.633, by adding a new paragraph (4), to include this requirement. A laboratory with a certificate of waiver must notify HHS before performing tests

that are not included in the waiver test list. We will issue a registration certificate for the new services (that is, a restricted registration certificate) authorizing the laboratory to initiate the new testing until we can determine compliance with Federal requirements. The laboratory will be able to continue all other testing specified on its certificate of waiver. Proposed § 493.633 has been revised to reflect that a registration certificate will be issued to allow a laboratory with a certificate of waiver to initiate testing in an area not listed on its certificate.

Comment: One commenter indicated that the proposed rule does not specify a time period for reporting the addition of new test procedures and recommended that laboratories be allowed at least 6 months to report such additions. This would permit laboratories time to introduce new testing services while gathering data to determine whether the laboratory can conduct the testing in a cost-effective quality manner.

Response: Section 493.633 has been revised to reflect the statutory requirements of section 353(d) of the PHSA. As indicated previously, a laboratory with a certificate or certificate of accreditation must notify HHS or the accreditation organization (as applicable) within 6 months of any changes in its scope of practice as indicated in section 353(d)(1)(A). However, as required by section 353(d)(2)(B), a laboratory with a certificate of waiver must obtain prior approval if it wishes to add testing not listed in the waiver test category.

Comment: One commenter stated that §§ 493.633(a) (1) and (2) were incompatible unless the word "changes" in paragraph (2) means "deletion" and excluded "additions." The commenter indicated that § 493.633(a)(1), which discusses performing tests not on the certificate, appears to be based on section 353(d)(2)(B) of the PHSA, which is limited to laboratories holding certificates of waiver. Therefore, this part of the regulation should be limited to certificate of waiver laboratories.

Response: The commenter is correct. As previously discussed, the regulation at § 493.633 has been revised accordingly.

Comment: One commenter expressed concern that there is no provision in the proposed regulation for assigning newly developed tests to a specialty or subspecialty of service, making it impossible for laboratories to know which personnel, quality control, etc. standards are applicable.

Response: Once CLIA is fully implemented, we will resolve any questions concerning the categorization of tests into the appropriate specialty or subspecialty of services. HHS will evaluate new technologies and methodologies for test categorization and inform laboratories of the Federal requirements that are applicable to the testing or examinations performed.

Section 493.634 Notification of Changes

Comment: One commenter indicated that the 30-day requirement for notification of changes in location would be burdensome. This commenter's clinic sites are located within community centers, schools, etc., and often must relocate on short notice. The commenter further indicated that 30 days would not allow the clinic sites sufficient time to notify HHS of the change.

Response: The regulation did not require that the laboratory notify HHS or its designee "prior" to a change in site, only that notification occur within 30 days of the actual relocation. Therefore, we do not believe that this requirement imposes an unreasonable burden, and we have retained the proposed language in the final rule. We have, however, determined that the notification requirements for changes in laboratory director should apply to laboratories issued a registration certificate to ensure that we have accurate information for program administration. We have revised the regulation to reflect this change. We have also added language to this section to reflect the same consequences of failure to notify HHS of changes as noted in § 493.633(b) for noncompliance with any of the requirements of part 493, and to reference § 493.639, the regulation section concerning the fees imposed for revising certificates as a result of changes in laboratory status.

Section 493.638 Registration Certificate and Certificate Fees

Comment: Two commenters specifically addressed the $261 proposed certificate fee and argued that the amount is too high. Another indicated that these fees will ultimately get passed on to the consumer and that it is entirely possible that access to laboratory testing will be reduced when small laboratories reduce their test menus to avoid certain CLIA fees or close down completely.

Response: In response to commenters' concerns, we have developed new fee schedules for certificates ($100, $350, and $600). The amount of the fee will be based on whether a laboratory is considered small, medium, or large (based on the volume and scope of testing performed by the laboratory.) These individual fee amounts do not reflect the actual resources needed to issue a registration certificate or certificate to each size group. However, the estimated total amount of fees generated under this graduated fee approach, along with the fees for compliance determination, is the amount we estimate is needed to cover the costs of the CLIA program. The graduated fee amounts have been adopted in order to avoid any undue burden on small laboratories, and it is our best attempt to structure the fee amounts in a way that maintains parity among the laboratories.

Comment: Two commenters encouraged us to publish an annual statement of income and expenses applicable to the CLIA program in the **Federal Register**.

Response: As with other HHS programs, the CLIA certification program will be audited periodically by the General Accounting Office and the Department's Office of the Inspector General. The results of these audits, designed specifically to determine HHS's accuracy in applying the mandates and guidelines of the programs, will be available to the public.

Comment: Section 493.638 addresses fees for waivers, indicating that, for a certificate of waiver, the fee "includes the cost of issuing the certificate of waiver, collection of fees and the administrative costs associated with evaluating tests to determine if a certificate of waiver should be issued." A commenter suggested that the language be changed to read: "* * * and the administrative costs associated with the evaluation of applications to determine if a certificate of waiver should be issued."

Response: We are not adopting the suggestion. The costs associated with evaluating the application for issuance of a certificate of waiver are included in the costs of issuing the certificate of waiver. Additional costs associated with the evaluation of tests for inclusion on the list of waiver tests are also included in the fee for issuance of certificates of waiver, as are other administrative costs associated with the operation of the program (for example, the cost of the billing system). In addition, we have revised proposed § 493.643(e) (now redesignated as § 493.643(d)) by adding a new subparagraph (2) to address the costs associated with complaint investigations. We specify that, if it is necessary to conduct a complaint investigation, impose sanctions, or conduct a hearing, HHS assesses the involved laboratory a fee to cover the

cost of these activities if the complaint is substantiated or the adverse action upheld. In the proposed rule, through an oversight, this was discussed only in § 493.645(h) with respect to laboratories issued a certificate of accreditation.

Section 493.639 Fee for Revised Certificate

Comment: One commenter believed that the administrative costs for the various regulatory services necessary to issue revised certificates, based on the actual cost of the resources and time involved, are too open-ended. The commenter suggested that an estimated fee for such services should be established and published.

Response: Costs for revising a certificate will be based on the administrative cost of processing the request for revision and issuing the revised certificate. A laboratory must inform us of any changes in the information on which the registration or other certificate is based.

Revisions in the registration certificate are required if changes occur in the laboratory's name or location. Revisions in regular certificates, certificates of accreditation, or certificates of waiver are necessary if the laboratory changes its name, location, or director, or if a laboratory with a "regular" certificate or certificate of accreditation adds services not included in the specialties or subspecialties listed on the certificate or deletes services that are included on its certificate. If a laboratory with a certificate of waiver adds tests that require issuance of a regular certificate, a registration certificate to cover the new testing will be required to enable the laboratory to conduct testing in the added services until a compliance determination can be made. Following a determination of compliance, a certificate will be issued and a fee for issuance of a certificate will be assessed.

We have reexamined our estimate of the time that would be necessary to issue a revised certificate and have determined that our original estimate was too long. We now estimate ½ hour (at $50 per hour) for Federal administration and ½ hour (at $50 per hour) for contractor administration. This results in a fee of $50 for a revised certificate.

We adjusted our time requirements downward to account for the fact that a nominal amount of time would be required to analyze and enter the revised application into the system and to issue a revised certificate. We believe that the analysis burden and direct data entry for a revised application is much less than for a regular application. In addition, the required contractor burden and the burden to the HHS data base to issue a revised certificate is much less than for a certificate. The initial certificate of registration cost of $100 to $600 includes significant costs incurred by HHS to administratively establish CLIA through development of regulations and required revisions; development of requests for contracts; development and maintenance of a complex data system; and development and updating of comprehensive manual and instructional guides. We have eliminated these large overhead administrative costs from the cost of issuing revised certificates.

If, for any of the certificates, a survey to determine compliance is necessary because of any of the changes, a laboratory must pay, in addition to the fee for issuing the revised certificate, the costs incurred to evaluate the changes.

Section § 493.643 Fee for Determination of Program Compliance

Comment: A commenter encouraged us to simplify the entire process by making random spot checks of physicians' offices without warning, with no fees, guidelines, or periodic evaluations.

Response: Section 353(g) of the PHSA requires compliance inspections, and section 353(c)(2) specifies that a certificate is valid for no more than 2 years. Therefore, we intend that each laboratory subject to the provisions of CLIA (other than those waived or State-exempt) receive at least a biennial inspection. We have an agreement with States to utilize and pay their survey agency staff to conduct these inspections on our behalf. CLIA legislation states that the costs incurred in implementing the laboratory certification program be borne by the laboratories themselves through user fees. This is true for all laboratories subject to CLIA regardless of type (and this includes physician office labs). Only if a laboratory is operating pursuant to a certificate of waiver will it not be subject to routine inspections.

Comment: A commenter contended that the system as proposed seems to focus more on the opportunity to assess and collect charges than to assure the laboratories' quality and cites that additional charges are to be imposed for follow-up visits, sanctions, and appeals. The commenter believed that charging for each sanction would appear to encourage the inspectors to find problems, while fees for appealing these findings could discourage the laboratories from using the appeals process.

Response: We disagree with the comment. The commenter's argument might be valid if State agencies were paid on the basis of numbers of problems cited or separate instances of sanctions to be applied to a deficient laboratory. However, the fees for determining compliance were developed in such a way that States are paid regardless of their findings of compliance or noncompliance, or instances of sanction actions. If upon reconsideration or appeal, the findings are not upheld, the laboratory is not responsible for these costs.

Comment: A commenter suggested that, because the CLIA implementation schedule is slipping, the effective dates for the fee collections will need to be revised.

Response: We decided to postpone collection of the fees until the CLIA standards regulation (HSQ–176–F) was published and, therefore, we are publishing both the fee and the standards regulations at the same time.

Comment: A State Health Department expressed concern that a State might have to absorb the costs associated with a hearing if a State takes a laboratory through a hearings process and the Administrative Law Judge (ALJ) rules in favor of the laboratory.

Response: We have taken into consideration the State agency's costs and time associated with participation in the hearings process. A laboratory that receives a favorable hearing decision will not pay any hearings costs. States will be fully paid for all reasonable costs associated with the enforcement of CLIA requirements.

Comment: A commenter expressed concern that laboratories should not have to face unwarranted fees which result from unnecessary inspections and investigations. The commenter suggested that the rule be clarified to ensure that laboratories are charged only for follow-up inspections when necessitated by the laboratory and not due to the failure of the inspector to allow adequate time and/or have adequate resources to complete the inspection on the initial visit; are charged for complaint investigations only when the complaint is shown to be valid; and charged for sanctions or hearings only when the laboratory is shown, after appeals, to have violated the requirements of CLIA.

Response: We agree that laboratories should not be burdened with inappropriate or unjustified fees. The fees are designed to determine a laboratory's compliance with program requirements. Follow-up inspections will occur only to determine whether a

laboratory found to be in non-compliance has corrected the cited deficiencies. State surveyors who determine laboratory compliance with CLIA requirements are not paid by the numbers of problems cited nor the numbers of sanctions applied. We believe that we have clearly stated in this rule that the fees to be assessed for complaint investigations or sanction activities will be for those that are substantiated.

Comment: Several commenters stated that the costs proposed for certification and inspection appear exorbitant. Another added that the costs are detrimental to small laboratories and hospitals that are barely solvent. Administration of the proposed fee schedule, the commenter continued, would discourage laboratories from offering a broader spectrum of tests since they would be monetarily at risk for expanding their services.

Response: We disagree that the fees are exorbitant. We recognize that some laboratories may experience more financial difficulty than others in meeting the requirements of CLIA. However, CLIA legislation requires that all laboratories subject to its provisions be assessed fees for certification and laboratories not issued a certificate of waiver be charged a fee for inspection and that these fees must be sufficient to cover all costs involved. In developing the fees for certification and compliance determination, we considered average time estimated and average surveyor pay scales across the country. These estimates also consider laboratory size based on types of specialties and volume of tests. In addition, we have established a lower fee within Schedule A for low-volume laboratories conducting less than 2,000 tests per year. As we gain experience from administering the CLIA program, we intend to revise the fee schedules as necessary.

Comment: A commenter said that the classifications in the proposed rule appear incomplete and unclear and make it difficult for pediatricians to determine the scope of the testing procedures and their corresponding fee responsibilities. HHS is obligated, the commenter continued, to make these explicit and understandable to prevent needless errors in filing applications, delays in issuing certificates, and excessive denials. A question which followed asked, if strep tests are performed using immunochemistry procedures, would the testing be classified an immunology, chemistry, or microbiology?

Response: The specialties/subspecialties listed in the preamble correlate with current terminology used to classify tests performed in Medicare and interstate licensed laboratories. We do not classify methodologies, technologies, or instrumentation; rather, classification is based on the constituent analyzed, measured, or identified. Direct strep antigen detection procedures are categorized in the subspecialty of bacteriology because the *Streptococcus* organism is detected and identified.

Section 493.643 Fee for Determination of Program Compliance

Comment: In the preamble of the proposed rule, we specifically invited comments on the type of methodology, process, and schedule to be used in updating the estimated fees for compliance determination surveys. We received 11 comments concerning the grouping of the 10 schedules and the number of specialties within each schedule. A summary of the comments follows:

—Six commenters argued against the number of specialties and/or volume of tests per schedule. Two of these suggested that schedules A and B be combined, as well as schedules C and D.

—Two more suggest that the schedules, as proposed, will unfairly affect smaller laboratories.

—Two Women, Infants, and Children (WIC) program clinics said that the schedules, as proposed, will seriously jeopardize their budgets, especially in light of the simple screening procedures they offer.

—Another commenter suggested that the large majority of laboratories conduct fewer than 10,000 tests per year.

Response: The schedules that were listed in the proposed rule were compiled using the currently available data from State survey agencies and HHS regarding estimated time and costs to determine program compliance with CLIA requirements. We had originally planned to propose a very limited number of schedules to encompass small, medium, and large laboratories. However, we believe that a larger number of schedules, such as 10, results in lower increments in fee amounts from one schedule to the next than would be so with fewer schedules and will allow the smaller laboratories to pay the least amount necessary to cover the costs of implementing CLIA's requirements. In this final rule, we will recognize within Schedule A, those low-volume laboratories that conduct 2,000 or fewer tests per year. We have established a separate, reduced compliance determination fee for these entities. As we gain experience with the timeframes and costs involved in determining laboratory compliance with CLIA requirements, we will reanalyze the fee-setting methodologies and intend to seek input from the public and make adjustments as necessary in size and volume ratios.

Comment: In the preamble of the proposed rule, we specifically invited comments on the definition of a test and on the feasibility of collecting test information, particularly in the area of quantitative testing. Several commenters responded to this request and indicated that assessing a facility's work volume by counting each analyte tested would be burdensome. One commenter indicated that this definition inflates the actual workload of the laboratory since from a laboratory perspective a test panel or profile (which includes multiple analytes) is really a selection of tests that are generally performed in a group or in combination. Commenters suggested the following alternatives to the proposed definition of a test:

—Define a test as a current procedural terminology (CPT) codeable charge with the codes (range of codes) identified and routinely updated by HHS.

—Define a test as a single reportable patient result, thus excluding tests on quality control samples from the annual test volume.

—Use the number of specimens analyzed rather than the number of tests to determine laboratory volume.

—Determine laboratory volume based on the type of laboratory factored by the number of employees, rather than tests.

Response: We appreciate the suggestions offered by the commenters. However we cannot define a test as a CPT codeable charge because profiles are included on the CPT codes and this would not reflect the actual laboratory testing activity involved in conducting the testing and determining the test results. The same holds true for the suggestion of using the number of specimens; each specimen could have multiple tests and would not be reflective of the actual laboratory performance. We do not believe that the suggestion for using a factor of the number of employees is feasible since this would encourage laboratories to employ fewer personnel and could have adverse implications on the quality of the laboratory services provided.

We do agree that tests run on quality control samples should not be included when calculating the annual volume of laboratory tests and have modified proposed § 493.638, "Registration

certificate and certificate fees," and § 493.643(d) (1) and (2) (now redesignated as § 493.643(c) (1) and (2)) to indicate that, when determining annual volume, tests performed for quality control, quality assurance and proficiency testing are to be excluded.

Section 493.645 Additional fee(s) for Accredited Laboratories (and State-exempt Laboratories)

Comment: A commenter, in discussing fees to be paid for complaint investigations, sanctions, or hearings, said that if we will assess fees and costs where the investigated laboratory is unsuccessful, the investigated laboratory should also be entitled to some of its costs should proposed adverse actions be found to be without foundation.

Response: We cannot accept this comment. The law provides no authority to pay costs of laboratories that are either successful or unsuccessful at an ALJ hearing.

Comment: Another commenter said that our assessment of fees against laboratories certified by other agencies is not appropriate since the laboratories have already incurred substantial costs in complying with accreditation programs standards. If HHS has concerns about the certification process of accreditation programs, it should collect fees from the accreditation programs. As an alternative, the commenter continues, HHS should not reinspect laboratories but acknowledge that inspections conducted by private nonprofit organizations if it appears that their standards are higher than HHS's.

Response: We are adopting this suggestion in part. CLIA does not provide authority for billing accreditation programs for the costs of monitoring their programs. CLIA mandates the assessment of fees from the individual laboratories. We are required by section 353(e)(2) of the PHSA to monitor the survey process of accrediting bodies and routinely scrutinize the standards and accreditation procedures of these entities to ensure that the standards applied are at least equal to the standards established by HHS. To accomplish this, a sample of accredited laboratories will be surveyed, with the costs shared by all accredited laboratories. The fee for a certificate of accreditation will include a proportionate share (based on our best estimate of the number of accredited laboratories) of the administrative costs associated with CLIA (including the cost of issuing the certificate) and a proportionate share of the cost of the monitoring surveys.

However, section 353(p) of PHSA indicates that if the Secretary determines equivalency of a State's licensure standards, the Secretary may exempt laboratories licensed in that State from the CLIA requirements, including the payment of fees. As previously discussed, we are exercising that authority and have revised the proposed regulation to reflect this change. While State-exempt laboratories are exempt from CLIA requirements, Federal inspections may be conducted at random to ensure that standards are being enforced in an appropriate manner. States will be billed for the random Federal inspections of their State-exempt laboratories and for their proprotionate share of the general overhead costs for the development and implementation of CLIA.

Comment: Referring to the additional fee an accredited laboratory will pay to cover the cost of evaluating individual laboratories in accreditation programs, a commenter said that these additional costs will be unnecessarily burdensome because they will also have to pay their own biennial inspection fees. Further, the commenter suggests that we should consider the possibility that many different accreditation programs may be approved and that we should conduct random sampling of each accreditation program, as opposed to a 5 percent sample of all accredited laboratories as proposed.

Response: As we have stated, CLIA legislation requires that the fees imposed on laboratories be sufficient to cover the costs of evaluating and monitoring accrediting bodies. The legislation also requires ongoing evaluation of accreditation programs and requires the assessment of fees to cover the costs of evaluating and monitoring accreditation programs. Regarding the sampling approach for evaluating accreditation programs, we agree that a 5 percent sample of laboratories accredited by each accrediting program that we have approved will provide more assurance of quality and accuracy than selecting 5 percent from the "total universe" of accredited laboratories. However, we have deleted the 5 percent provision that appeared in proposed § 493.645 since that provision reflects only an administrative goal, not a fixed obligation of the Department. We will administratively implement the commenter's suggestion to attain the 5 percent sample goal. In addition, although State-exempt laboratories have been exempted from CLIA requirements, such laboratories will be subject to Federal inspections. We intend to conduct inspections of a 5 percent sample of State-exempt laboratories to ensure that standards are being enforced in an appropriate manner. Costs of such inspections will be paid by the State licensure program. Section 493.645 has been revised to include State-exempt laboratories.

Comment: A commenter referred to apparent discrepancies between preamble and regulatory language involving the financial obligation of an accredited laboratory subject to a complaint investigation. The commenter would like to have us clarify that all costs (that is, for the complaint investigation, any sanctions, or hearings) would be dismissed if the complaint is found to be unsubstantiated.

Response: As stated earlier, through an oversight, the regulatory language only addressed the costs associated with complaint investigations in regard to laboratories issued a certificate of accreditation (§ 493.645(b)). We have corrected this by adding a new § 493.643(d)(2), which specifies that costs for unsubstantiated complaint investigations or sanctions/hearings activities would not be imposed on the laboratory. We have also revised proposed § 463.645 to specify that the State licensure program may be assessed the costs incurred for complaint investigations of State-exempt laboratories if the complaint is substantiated.

Section 493.646 Payment of Fees

As indicated earlier, in response to comments received on the proposed regulation, we have made revisions to the proposed fee amounts. Charts showing the bases for the revised fee amounts are included at the end of the comment and response section.

Comment: A commenter representing multiple clinics within a State indicated that costs to purchase equipment for hematocrit testing in order to be eligible for a certificate of waiver would be prohibitive.

Response: CLIA anticipates that the regulations will be enforced at each location where tests are performed. Section 353(b) of the PHSA specifically states that a laboratory must have in effect an HHS-issued certificate (that is, a certificate, registration certificate, certificate of accreditation, or certificate of waiver) that is applicable to the specialty or subspecialties of services being offered. We will require that a separate application be filed for each laboratory location. Consequently, we will not allow laboratories located at different street addresses to apply for a

single certificate to cover all locations. However, we are providing some flexibility to a hospital that has multiple laboratory components that are at the same address and under common directorship to apply for a single certificate. In addition, laboratories that do limited testing (that is, few types of tests) for screening or treatment of individuals that are directed by not-for-profit or Federal, State, or local government organizations (for example, the WIC program) can operate (at their option) under one certificate.

Comment: In discussing fees for waivers, two commenters said that they could support a waiver fee of $100 (one of the two added that glucose, cholesterol, and hematocrits should be included as waived tests).

Response: We agree with the comment that the proposed waiver fee of $156 is too high. We have, in this final rule, therefore, revised the cost of issuing a certificate of waiver to $100. This reduction is based primarily on recalculations of the administrative effort required to issue a certificate of waiver and on estimates of the number of laboratories that may be able to qualify for waiver.

As previously mentioned, the classification of tests is addressed in the final CLIA rule, HSQ–176–F, appearing elsewhere in this Federal Register.

Comment: A commenter stated that the fees as proposed will hinder cost-effective testing in smaller sites and that they should be re-analyzed based on comments and subsequent analysis of an earlier rule dealing with the variety of laboratory levels and personnel requirements.

Response: We disagree that the fees will hinder cost-effective testing. The fees are designed to cover the costs we will incur to evaluate compliance of large and small testing operations and the cost associated with establishing standards under CLIA, as well as all contractor-related costs. The commenter's suggestion that the fees be re-analyzed is valid. We will review the fee schedules once the Federal health and safety requirements are established based on test complexity. We will also, on an actual basis, review the fee schedules in light of actual experience.

Comment: The above commenter also suggested that laboratories be allowed to submit a deposit of $25 with each initial application, with the balance due during the second year of the 2-year fee cycle. This would afford us quicker access to funding in order to begin implementing CLIA.

Response: We are not adopting this suggestion. Although the commenter is certainly correct about the gross amount such a proposal could provide, we believe that the accounting and reporting costs associated with tracking the remittances of all laboratories subject to CLIA would be extremely high. As stated earlier, we have postponed assessing fees until the final CLIA standards rule (HSQ–176–F) was published. Now that HSQ–176–F is published elsewhere in this Federal Register, we will begin to send out applications and bills to laboratories. The amount of the bill will be based on the information provided by the laboratory in response to the questionnaire mailed earlier and will be for the full amount (that is, $100, $350, or $600). This should provide sufficient funding in order to begin implementing CLIA.

Comment: One commenter suggested that we incorrectly assumed that most of physician office laboratories would fall within the waiver category and consequently require a minimum of Federal and State resources and time. The commenter continued that, if we based the fee schedules and other estimates of administrative costs on this, probably faulty assumption, insufficient funds will be collected to cover CLIA costs. Fees, then, will have to be substantially increased during the second year of CLIA implementation.

Response: We disagree with the comment. We estimated the resources and time necessary to conduct compliance determinations based on the volume and scope of laboratories services. Although these are only estimates, they are not arbitrary. They were developed after collaboration with State Health Departments and other Federal agencies. If we find that our estimates are, in fact, incorrect, we will revise the fee schedules accordingly and will publish them for public review in the Federal Register.

Comment: Regarding the assessment of fees for the issuance and renewal of certificates of waiver, a commenter suggested that, should these fees be assessed to nursing facilities and intermediate care facilities for the mentally retarded, they should be considered allowable costs under Medicare and Medicaid for payment rate purposes.

Response: We agree with the intent of the comment. User fees for laboratories within either a participating nursing facility or intermediate care facility for the mentally retarded are allowable costs that states should take into account as part of their facility payment rates.

Comment: A commenter indicated that there are currently regional differences considered in the Medicare program's payments to physicians, depending on where in the country they practice medicine. The commenter continued that CLIA should take into consideration the concept of regional fees to be based on the laboratory's size and payment potential.

Response: We are not adopting regional fees. The fees for compliance determination contained in this rule take into consideration individual State variances such as geographic locations, travel costs, and State civil service pay scales. Therefore, State differences have been considered with regard to high and low cost areas.

Comment: A commenter, in discussing the fees for certification and determining compliance, suggested that the application and the fees for certification could be considered on the sliding scale of criteria according to hospital size and laboratory services.

Response: We have adopted this approach in part. A laboratory should be considered a separate entity and not necessarily linked to the size or operation of a hospital (in which many laboratories may be located). In the preamble of the proposed rule, we have outlined CLIA's scope by listing those "entities that perform laboratory testing" in the various types of facilities. But throughout the preamble and, more importantly, throughout the legislation itself, laboratories are treated as separate entities to which CLIA's unique provisions apply. We have, however, considered individual laboratory "size" based on number of specialties or scope of services performed and test volume in order to establish an appropriate range of fees.

Comment: A commenter indicated that some of the fees as currently proposed seem to affect smaller laboratories unfairly, resulting ultimately in inequitably high per test costs. Further, the commenter contended that such high per test fees for small laboratories could adversely affect patient access and that some small laboratories might even be forced to close.

Response: We disagree with this comment. We have considered small laboratories by establishing varying rates depending on volume and laboratory size. The ten proposed schedules, including a new low-volume category within Schedule A, attempt to minimize the negative impact on smaller laboratories. We intend to seek input from the public and will adjust the fee schedules as better data becomes available.

Comment: Responding to our solicitation for comments on existing

inspection experience with numbers and groupings of laboratories, a commenter offered that our proposed ten schedules could easily be reduced to five.

Response: We placed laboratories within the ten-schedule structure after conducting detailed analyses of information available on the amount of time necessary and the number of people required to determine laboratory compliance. We also believe that a ten-schedule structure is more beneficial since, by having the larger number of schedules, laboratories will more likely find themselves grouped more homogeneously. In addition, we have included another fee within Schedule A for low-volume laboratories that conduct 2,000 or fewer tests per year. As experience is gained in applying these fee schedules on all testing sites, we intend to seek input from the public and will revise them as appropriate.

Comment: Another commenter, responding to our request for comments on existing inspection experience and how it may relate to CLIA, objected strongly to the proposed fees and cites his State's $300 annual laboratory regulation program as being more realistic.

Response: We acknowledge that there may be significant differences in the amounts charged by an individual State's laboratory regulation program and the fee schedules proposed in this rule. These differences may be the result of a number of factors, including the extensive requirements contained in CLIA and the mandate that all costs incurred, including contractural and administrative costs, are to be borne by the laboratories. We have developed fees to cover all Federal, State, and contractor costs, as well as the costs for certificate issuance and for compliance determination, based on projections of costs to administer CLIA. These fees are subject to revision based on actual experience.

Section 493.649 Methodology for Determining Fee Amount

Comment: A commenter disagreed with our methodology for determining fee amounts, arguing that basing the fees on estimates of time needed to complete the survey and assessment of individual tests is cumbersome and subject to varied interpretation. Further, the commenter continued, time estimates will not allow a laboratory requesting certification to accurately project its costs.

Response: We disagree with the comment. We believe that basing survey costs on time estimates is an accurate approach to fee development. CLIA legislation includes the mandate that the costs for certification activities be borne by the laboratories. Since 1966, we have had in place an agreement through which we pay State agencies to determine program compliance through monitoring proficiency testing, evaluating personnel qualifications, and onsite surveys. Payment for these survey activities are negotiated with the States based on the number of people and the time estimated for the survey workload; in this case, on the time estimated to determine a laboratory's compliance with the various proficiency testing, personnel, recordkeeping, quality control, and quality assurance requirements of CLIA.

Comment: Another commenter addressing the methodology used to determine the fee amount expressed concern that we intend to use some of the CLIA revenues to fund studies and research not statutorily mandated by the legislation. The commenter believed that only mandated studies should be so funded.

Response: CLIA provides that fees assessed are to be sufficient to meet the costs incurred in administering the program. If studies and research are required to improve specific approaches to the development of laboratory regulations and survey and certification activities, regardless of whether they are specifically mentioned in CLIA, the costs of those studies become integral to the proper and efficient administration of CLIA and, as such, are to be borne by the laboratory community.

Basis for Fee Amounts

The fee schedules listed herein are designed to generate sufficient revenues to fully cover Federal costs for the development, administration, and implementation of CLIA, as required by law. They are based on the Department's best estimates regarding the number and testing volume of laboratories to be regulated, as well as estimates of associated Federal costs. As more definitive information becomes available as a result of the registration process, the fees for certificates of accreditation, inspection, and compliance will be reviewed and may require adjustment upward or downward.

The fees laboratories must pay for the issuance of a registration certificate or a certificate are as follows:

Small laboratory, that is, a laboratory categorized in this rule as Schedule A (including Low-Volume), Schedule B, or Schedule C	$100
Medium laboratory, that is, a laboratory categorized in this rule as Schedule D, Schedule E, Schedule F, or Schedule G	350
Large laboratory, that is, a laboratory categorized in this rule as Schedule H, Schedule I, or Schedule J	600

Note: The fee amount for a revised certificate of any type is $50.

A certificate of waiver or certificate of accreditation fee would be assessed as follows:

Functions or tasks for all laboratories	Hours needed	Hourly rate	User fee
Federal Administration	1	$50	$50
Contractor Administration	1	50	50
TOTAL			100

(The hourly rate of $50 for Federal Administration includes approximately $30 for salaries and fringe benefits, and approximately $20 for overhead costs, including the support of a nationwide satellite training network.)

The hours required for biennial inspections are a fixed national number by category; however, since the hourly rate varies by State, there will, in effect, be 53 separate fee schedules for biennial inspections. The average time and cost required to determine compliance during calendar year 1992 would be as follows:

	Hours	Average [1] hourly rate	Biennial user fee
Schedule A Low-volume Laboratories			$300
Schedule A Laboratories:			
[2] Biennial inspection	24	$35	$840
Followup visit or complaint investigation	15	35	525
Sanctions/ Hearings	8	35	280
Schedule B Laboratories:			
[2] Biennial inspection	32	35	1,120
Followup visit or complaint investigation	17	35	595
Sanctions/ Hearings	9	35	315
Schedule C Laboratories:			
[2] Biennial inspection	40	35	1,400
Followup visit or complaint investigation	19	35	665
Sanctions/ Hearings	10	35	350
Schedule D Laboratories:			
[2] Biennial inspection	47	35	1,645
Followup visit or complaint investigation	21	35	735

	Hours	Average [1] hourly rate	Biennial user fee
Sanctions/ Hearings	11	35	385
Schedule E Laboratories:			
[2] Biennial inspection	54	35	1,890
Followup visit or complaint investigation	24	35	840
Sanctions/ Hearings	12	35	420
Schedule F Laboratories:			
[2] Biennial inspection	61	35	2,135
Followup visit or complaint investigation	26	35	910
Sanctions/ Hearings	13	35	455
Schedule G Laboratories:			
[2] Biennial inspection	68	35	2,380
Followup visit or complaint investigation	28	35	980
Sanctions/ Hearings	14	35	490
Schedule H Laboratories:			
[2] Biennial inspection	75	35	2,625
Followup visit or complaint investigation	30	35	1,050
Sanctions/ Hearings	15	35	525
Schedule I Laboratories:			
[2] Biennial inspection	82	35	2,870
Followup visit or complaint investigation	32	35	1,120
Sanctions/ Hearings	16	35	560
Schedule J Laboratories:			

[2] Biennial inspection—The sum of 82 hours plus 7 hours for each additional 500,000 tests or portion thereof multiplied by a $35 hourly rate.

Followup visit or complaint investigation—The sum of 32 plus 2 hours for each additional 500,000 tests or portion thereof multiplied by a $35 hourly rate.

Sanctions/Hearings—The sum of 16 hours plus 1 hour for each additional 500,000 tests or portion thereof multiplied by a $35 hourly rate.

[1] Average hourly rates and user fees are shown since individual contracts are negotiated with 53 State survey agencies. The actual user fee for determining compliance would depend upon the State in which the laboratory is located. For the purpose of the unit cost budget methodology, the $35 is broken out by two components: actual surveyor time to conduct compliance evaluations, which is about $27 per hour, which includes but is not necessarily limited to preparation, travel, and report writing time; and an adjustment of $8 per hour to cover surveyor costs for holidays, vacation, sick leave, and attendance at training courses. Therefore, the cost of these other work-related activities has been included in the user fee methodology.

[2] While the hours for the biennial surveys are fixed, the hours necessary for followup visits, complaint investigations and sanction/hearings activities will be the actual number of hours involved. (We show averages in the chart above for illustrative purposes.) The fee to be assessed, therefore, will vary depending on the actual time spent and the State's hourly rate.

The $300 biennial inspection fee for Low-Volume laboratories is a fixed fee, regardless of the State's hourly rate. We anticipate relatively little followup, complaint investigations, etc., for this grouping of laboratories and do not intend to charge them separately for these activities. The costs for these activities will be subsumed as part of the $300 fee.

Includes evaluating qualifications of personnel; monitoring proficiency testing; conducting onsite surveys; developing deficiency statements; and evaluating laboratories' plans to correct deficiencies.

In addition to the certificate of accreditation fee, the fee that a laboratory issued a certificate of accreditation would pay [1] in calendar year 1992 to share the cost of the 5 percent random inspections discussed earlier would be:

Schedule A Laboratories	$42
Schedule B Laboratories	56
Schedule C Laboratories	70
Schedule D Laboratories	82
Schedule E Laboratories	95
Schedule F Laboratories	107
Schedule G Laboratories	119
Schedule H Laboratories	131
Schedule I Laboratories	144
Schedule J Laboratories	[1]

[1] Schedule I base fee plus $12 for each additional 500,000 tests or portion thereof.

Note: The above schedules and corresponding fees also apply to the 5 percent annual random inspection of State-exempt laboratories. State-exempt laboratories will not be billed for these amounts. Rather, their State must pay these fees.

The fee that a laboratory issued a certificate of accreditation would pay, if it is necessary to perform the following activities in the case of that particular laboratory during 1992, would be as follows. (In this final rule, we are likewise associating the following costs for State-exempt laboratories. These laboratories will not be billed the following amounts; rather, their respective State must pay all costs associated with these activities.)

Follow-up Visits or Complaint Investigations

Schedule A Laboratories	$525
Schedule B Laboratories	595
Schedule C Laboratories	665
Schedule D Laboratories	735
Schedule E Laboratories	840
Schedule F Laboratories	910
Schedule G Laboratories	980
Schedule H Laboratories	1,050
Schedule I Laboratories	1,120
Schedule J Laboratories	[1]

[1] Schedule I base fee plus $70 for each additional 500,000 tests or portion thereof.

[1] Includes evaluating qualifications of personnel; monitoring proficiency testing; conducting onsite surveys; developing deficiency statements; and evaluating laboratories plans to correct deficiencies.

A laboratory will be billed the above amounts for its certificate of accreditation when its accreditation organization has been approved by HHS.

Sanctions/Hearing

Schedule A Laboratories	$280
Schedule B Laboratories	315
Schedule C Laboratories	350
Schedule D Laboratories	385
Schedule E Laboratories	420
Schedule F Laboratories	455
Schedule G Laboratories	490
Schedule H Laboratories	525
Schedule I Laboratories	560
Schedule J Laboratories	[1]

[1] Schedule I base fee plus $35 for each additional 500,000 tests or portion thereof.

All laboratories subject to inspection are required to pay the amount representing the biennial inspection costs in the aforementioned schedules. If the laboratory requires additional survey time as a result of followup visit(s), certificate revisions, complaint investigation(s) that are substantiated, intermediate sanctions, appeals or hearings, an additional assessment, based on actual costs, will be made for such activities.

V. Summary of Changes in the Final Regulations

As stated in our response to comments, we have made changes to the proposed regulations published August 3, 1990. With the exception of the changes identified below, the final regulations reflect the proposals made in the August 3, 1990 proposed rule.

- We have retitled the "provisional" certificate as a "registration" certificate. We have made this change throughout the rule.
- We have revised proposed § 493.602, "Scope of subpart," to clarify that part 493, subpart F, applies to all laboratories "that test human specimens for health purposes." We have also added that it sets forth requirements related to State-exempt laboratories.
- We have changed "waiver test" or "certificate of waiver test" to "waived test" throughout this rule.
- We have revised proposed § 493.606, which concerns applicability, by replacing the proposed text with a cross reference to the applicability provisions of § 493.3, which is established in the standards regulation (HSQ–176–F) published elsewhere in this issue of the **Federal Register**.
- We have revised proposed § 493.610, which requires that laboratories have an appropriate certificate, to indicate that certificates of waiver will not be applicable to specialties or subspecialties of services. We are also revising this section to specify that a laboratory licensed by and located in a State whose licensure program is approved by HHS is exempt

from CLIA requirements and does not require a certificate issued by HHS.

• We have revised proposed § 493.614, which covers application procedures, to remove the distinction between (1) laboratories not licensed under CLIA '67 and laboratories not Medicare/Medicaid approved and (2) all other laboratories. The process for obtaining applications will be the same for both groups. We have further revised § 493.614 to specify that laboratories in a hospital that are located at the same address and under common directorship have the option of applying for a single certificate or multiple certificates. We also clarify that a laboratory that is not at a fixed location must file a single application using the address of its designated primary site. However a separate certificate is required for each unit that serves as a mobile laboratory. The certificate(s) would reflect the address of the primary site. Additionally, not-for-profit or Federal, State, or local government laboratories that engage in limited public health testing (few types of tests) at different street addresses may operate, at their option, under one certificate. We also have made a change in the punctuation in proposed paragraph (c) to indicate that the certificate of waiver will not apply to specialties or subspecialties of services.

We have further revised proposed paragraph (c), which specified that an application for a certificate of any type must be signed by the owner, operator, or authorized representative of the laboratory, by deleting reference to the operator. In reviewing this provision, we have concluded that if the laboratory owner wishes to authorize the laboratory operator to submit the various forms, he or she may do so, but it would be inappropriate for this regulation to independently empower the operator regardless of the laboratory owner's wishes. We have revised proposed paragraph (d) to clarify that tests for quality control, quality assurance, and proficiency testing purposes are not included when counting the number of tests performed annually. We further revised proposed § 493.614 to refer to licensing under CLIA '67 in the past tense, rather than the present, since CLIA '67 has been superseded by the Clinical Laboratory Improvement Amendments of 1988.

• We have revised proposed § 493.618, "Additional application requirements," to remove, from paragraph (b), the reference to the July 1, 1991 effective date, since this date has now occurred. We have also specified that the laboratory must agree to permit inspections by HHS's designee, as well as by HHS. In paragraph (d), we have removed the word "operator", for the same reason we removed it from § 493.614(c).

• We have revised proposed § 493.622, "Opportunity for a hearing," and retitled it "Appeals procedures," to clarify that any laboratory that has its certification denied or limited cannot operate as a laboratory under the PHSA in the areas covered by the limitation or denial unless the denial or limitation is overturned. We have also revised this section to more accurately reflect the appeals process for laboratories.

• We have revised proposed § 493.626, "Provisional certificate," by retitling it as "Registration certificate" and adding, in paragraph (a), that the registration certificate generally will not include specialties/subspecialties of service, but will authorize the entity to conduct laboratory testing until a determination of the appropriate level of compliance can be made. We have also revised paragraph (a) to indicate that laboratories that were licensed under CLIA '67 will also initially receive registration certificates. We have also made a change (not discussed elsewhere) to proposed paragraph (b). Proposed paragraph (b) specified that, prior to expiration of the provisional (now "registration") certificate, HHS would notify the laboratory of the applicable requirements to obtain the appropriate certificate. It also stated that HHS would initiate revocation or limitation of a laboratory's provisional (now "registration") certificate "for failure to comply with the applicable requirements as set forth in the notification by HHS * * *." We have revised this section to more accurately reflect the appeals process applicable under CLIA.

• As a change not discussed elsewhere in this preamble, we have revised proposed §§ 493.630, 493.631, and 493.632, which concern the requirements for a certificate, certificate of waiver, and certificate of accreditation, respectively, to add that each type of certificate is valid for not more than 2 years. This addition is consistent with the term specified in section 353(c)(2) of the PHSA.

• We have revised proposed § 493.630, "Certificate," by removing paragraph (a) and redesignating paragraph (b) as § 493.630. We then revised it to remove the distinction between laboratories that were licensed under CLIA '67 and those that were not.

• We have revised proposed § 493.632, "Certificate of accreditation," be changing "accreditation program" to "accreditation organization" in order to be consistent with the terminology used in other rules.

• We have revised proposed § 493.633, which addresses the applicability of the certificate, certificate of waiver, and certificate of accreditation to specify that a certificate of waiver is applicable to tests listed in the waiver test category. We have added that, if a laboratory with a certificate of waiver wishes to add services not included in the waived test category, it must notify HHS or its designee before performing the testing and that HHS will issue a registration certificate to authorize the laboratory to initiate testing. We specify that the limited registration certificate for the new testing is valid for 2 years or until a compliance determination can be conducted, whichever is shorter. We have also revised § 493.633 to reflect the statutory requirement that laboratories possessing a certificate or certificate of accreditation must agree to notify HHS or its designee or the accreditation organization (as appropriate) within 6 months of any changes in testing or methodologies.

Paragraph (b) of § 493.633 has been revised to indicate that various sanctions may be imposed upon a laboratory for failure to comply with the notification requirements of § 493.633 and to more accurately reflect the appeals process available with regard to such sanctions.

• We have redesignated the text of proposed § 493.634, "Notification of changes," as paragraph (a) and revised it to require that all laboratories, including those with registration certificates, must give notice of a change in director and to add that only laboratories performing Level II (retitled high complexity) testing are required to give notice of a change in supervisor. We have added new paragraphs (b) and (c). Paragraph (b) specifies that various sanctions may be imposed upon a laboratory for failure to comply with the notification requirements of § 493.634 and sets forth the appeals process available in such cases. We also specify that, for laboratories participating in Medicare and Medicaid, payments are suspended for failure to comply with the notification requirements. Paragraph (c) specifies that the laboratory must pay a fee for a revised certificate.

• We have revised §§ 493.638(b), 493.643(c) (1) and (2), which concern fees, to specify that tests performed for quality control, quality assurance, and proficiency testing purposes are excluded from the laboratory's annual volume. We have also revised

§ 493.638(b) to clarify, through the use of cross-references, the costs that are included in a fee schedule amount. Further, in recognition of the fact that those laboratories surveyed first may have to pay a certificate fee sooner than 2 years after paying the fee for a registration certificate, we have revised the reference to fee assessment and payment on an biennial basis to specify that the fee is assessed and payable at least biennially. We have also added that the fee for the issuance of the appropriate certificate is based on whether the laboratory is considered small, medium, or large.

• We have revised proposed § 493.639, "Fee for revised certificate," by redesignating it as paragraph (b) and adding a new paragraph (a) to specify that, if after a laboratory is issued a registration certificate, it changes its name or location, it must pay for a revised certificate. We have revised the paragraph redesignated as paragraph (b) to add that, if a laboratory with a certificate, certificate of accreditation, or certificate of waiver changes its name, location or its director or deletes services specified on its certificate, it must pay for a revised certificate. We also add that, if a laboratory with a certificate of waiver wishes to perform tests not included in the waiver test category, it also must pay for a registration certificate to allow the new testing.

Additionally (and not discussed elsewhere), we have deleted the word "actual" from the sentence "The fee for issuing an appropriate revised certificate is based on the actual cost to issue the revised certificate to the laboratory." We believe "actual cost" may be misread to imply that an adjustment of some sort would be made in each instance to reconcile estimated costs with incurred costs. In this preamble, we have established a fee of $50 (reducing it from the proposed estimated cost of $261). This represents our estimate of the average actual cost to issue a revised certificate. We do not believe that the small amount of any adjustment would justify the administrative burden (and cost) of adjusting the fee for individual laboratories.

• We have revised the proposed § 493.643, "Fee for determination of program compliance," by incorporating paragraph (b) into paragraph (a) and redesignating proposed paragraph (c) as paragraph (b). In redesignated paragraph (b), we have clarified that the fee for determining program compliance includes necessary administrative costs. Also, for clarification, we have moved the sentence regarding additional expenses in the proposed rule to the end of the paragraph and added a sentence at the end that specifies that the additional fee is based on actual resources and time necessary to perform the various activities.

In the redesignated paragraph (c), "Classification of laboratories that require inspection for purpose of determining amount of fee," in order to accommodate the concerns of small testing entities, we have established a new category within Schedule A for those laboratories performing no more than 2,000 laboratory tests per year.

We have revised proposed § 493.643(e) (now redesignated as § 493.643(d)), which addresses additional fees that a laboratory must pay, to add that, if an additional fee is assessed in connection with upgrading a certificate, failure to pay the fee will result in revocation of the certificate. We have also removed reference to a certificate of accreditation from this paragraph. Because compliance determinations of accredited laboratories are made by the accreditation organization, a HHS fee for compliance determination does not apply to these laboratories. We are also adding that, if it is necessary to conduct a complaint investigation, impose sanctions, or conduct a hearing, HHS assesses the involved laboratory (other than a State-exempt laboratory) a fee to cover the cost of these activities and that failure to pay this fee will result in the revocation of the certificate. We specify that, if a complaint investigation results in a complaint being unsubstantiated or if an HHS adverse action is overturned, the laboratory is not assessed the fees that would have covered the cost of these activities.

• We have revised proposed § 493.645, "Additional fee(s) for accredited laboratories," by changing its title to "Fee(s) applicable to accredited laboratories/approved State licensure programs." We have also deleted the provision that would have set a 5 percent inspection sample of all accredited laboratories since that number reflects only an administrative goal and not the kind of fixed obligation that the proposed rule might have suggested. We have also made revisions to specify that the State is assessed for the costs incurred for the inspection of State-exempt laboratories and for investigations of complaints against the State's State-exempt laboratories if the complaint is substantiated, and the State's prorata share of general overhead to develop and implement CLIA.

• We have revised proposed § 493.646, "Payment of fees," by redesignating the text as paragraph (a) and adding that State-exempt laboratories are not notified of fee amounts. We have also revised paragraph (a) to specify that HHS will advise the laboratory where to send payment. We removed the reference to commercial banks because it is possible that not all laboratories subject to CLIA will make payment to commercial banks. We have added a new paragraph (b), which specifies that, in the case of a State with an HHS-approved licensure program, the State is billed for the costs of validation surveys and the costs of complaint investigation of a State-exempt laboratory if the complaint is substantiated.

• We have revised proposed § 493.649, "Methodology for determining fee amount," to clarify that the hourly rate includes both the costs to perform the required activities and necessary administration costs. We also have added that the fee for issuance of the registration certificate or certificate is based on the laboratory's scope and volume of testing.

In addition to the above changes that have been made in the regulation, as a change from the preamble of our proposed rule, we are establishing $50 (and not $261) as the fee for issuing a revised certificate of any type. Additionally, we are establishing, within Schedule A, a separate fee ($300) for low-volume laboratories that conduct 2,000 or fewer tests per year. We are also revising the cost of issuing certificates and registration certificates from $261 across-the-board to $100, $350, or $600, depending on whether the laboratory is, respectively, a small, medium, or large facility (as defined in this preamble).

VI. Regulatory Impact Statement

Executive Order (E.O.) 12291 requires us to prepare and publish a final regulatory impact analysis for any proposed regulation that meets one of the E.O. 12291 criteria for a "major rule"; that is, that will be likely to result in—

• An annual effect on the economy of $100 million or more;

• A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

• Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

In addition, we generally prepare a final regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), unless the Secretary certifies that a final regulation will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we consider all laboratories as small entities. Individuals and States are not included in the definition of small entity.

In addition, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a final rule will have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 102(b) of the Act, we define a small rural hospital as a hospital that has fewer than 50 beds and is located outside a Metropolitan Statistical Area.

At the time we published the proposed rule (55 FR 31758, August 3, 1990), we indicated that these provisions constituted a major rule, and we provided a limited analysis. Since our analysis was not conclusive, we encouraged comments and submission of any applicable data concerning these provisions, particularly if there was a perception that they may result in significant increased costs. Although the overwhelming majority of the comments we received expressed concern over costs, specifically user fees, we received only general statements and no hard data. Further analysis of the requirements contained in this rule and of their impact on the public is incorporated in the Regulatory Impact Analysis for HSQ–176, the CLIA standards rule.

For the most part CLIA law requires that all laboratories be assessed fees for certification and inspection and that these fees should be sufficient to cover all costs involved. We fully expect to gain experience from administering the CLIA program and will reconsider our approach to establishing fee schedules, and we will revise schedules as necessary. We believe the majority of the costs alluded to by commenters are the result of a misunderstanding of the regulations or a result of the statute. Most of the costs mentioned by commenters are addressed in the comment and response section (section IV) of this final rule.

VII. Final Rule With Comment Period

In the proposed rule published on August 3, 1990, we proposed, in § 493.631, to issue a certificate of accreditation to laboratories licensed by a State whose licensure program had been approved by HHS. This final rule exempts such laboratories from the requirements of CLIA (§ 493.610) and requires the State to pay a fee for inspection of a sample number of these laboratories to ensure that standards are being enforced in an appropriate manner (§ 493.645(b)(1)). This final rule also requires the State to pay the cost of a complaint investigation of a State-exempt laboratory if the complaint is substantiated (§ 493.645(b)(2)). Further, this final rule also requires the State to pay its prorata share of general overhead to develop and implement CLIA (§ 493.645(b)(3)). As stated under "Comment period" in the DATES section of this preamble, we will accept comments on only the State fee provision that are received timely.

VIII. Collection of Information Requirements

Regulations at §§ 493.614, 493.618, 493.633(a), and 493.634 contain information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). A notice will be published in the **Federal Register** after approval is obtained. The information collection requirements concern information that must be provided on a laboratory's application for a registration certificate, certificate of waiver, certificate of accreditation, or certificate and subsequent notification of any changes in the information provided on the application. All laboratories would be required to provide the information.

Public reporting burden for this collection of information is estimated to be approximately 3 hours per application. Organizations and individuals desiring to submit comments on the information collection and recordkeeping requirements should direct them to the Office of Management and Budget, Office of Information and Regulatory Affairs, room 3002, New Executive Office Building, Washington, DC 20503, Attention: Allison Herron Eydt, HCFA Desk Officer.

List of Subjects in 42 CFR Part 493

Health facilities, Laboratories, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR part 493 is amended as follows:

PART 493—LABORATORY REQUIREMENTS

1. The authority citation for part 493 continues to read as follows:

Authority: Sec. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following 1861(s)(11), 1861(s)(12), 1861(s)(13), 1861(s)(14), 1861(s)(15), and 1861(s)(16) of the Social Security Act (42 U.S.C. 1302, 1395x(e), the sentence following 1395x(s)(11), 1395x(s)(12), 1395x(s)(13), 1395x(s)(14), 1395x(s)(15), and 1395x(s)(16)).

2. A new subpart F is added to part 493 to read as follows:

Subpart F—General Administration

Sec.

493.602 Scope of subpart.
493.606 Applicability of subpart.
493.610 Certificate requirements for laboratories.
493.614 Application procedures.
493.618 Additional application requirements.
493.622 Appeals procedures.
493.626 Registration certificate.
493.630 Certificate.
493.631 Certificate of waiver.
493.632 Certificate of accreditation.
493.633 Applicability of certificate, certificate of waiver, and certificate of accreditation.
493.634 Notification of changes.
493.638 Registration certificate and certificate fees.
493.639 Fee for revised certificate.
493.643 Fee for determination of program compliance.
493.645 Fee(s) applicable to accredited laboratories/approved State licensure programs.
493.646 Payment of fees.
493.649 Methodology for determining fee amount.

Subpart F—General Administration

§ 493.602 Scope of subpart.

This subpart sets forth requirements all laboratories that test human specimens for health purposes must meet in order to apply for and be issued a registration certificate, certificate of waiver, certificate of accreditation, or certificate under section 353 of the Public Health Service Act (42 U.S.C. 263a). It also sets forth the methodology for determining the amount of the fees for issuing registration certificates, certificates of waiver, certificates of accreditation, or certificates and for determining compliance with the applicable standards of the Public Health Service Act (the PHS Act) and the Federal validation of State-exempt laboratories.

§ 493.606 Applicability of subpart.

The rules of this subpart are applicable to those laboratories specified in § 493.3.

§ 493.610 Certificate requirements for laboratories.

(a) Except as specified in paragraph (b), no person may solicit or accept

materials derived from the human body for laboratory examination or other procedure unless there is in effect for the laboratory a registration certificate or a certificate of waiver issued by HHS, or a certificate or a certificate of accreditation issued by HHS that is applicable to the specialty or subspecialties of services offered by the laboratory.

(b) A laboratory licensed by a State whose licensure program is approved by HHS is exempt from CLIA requirements (that is, State-exempt) and does not require a certificate issued by HHS.

§ 493.614 Application procedures.

(a) HHS or its designee will send an application to those laboratories it has identified as potentially being subject to the requirements of CLIA. Those laboratories that do not receive an application must contact HHS or its designee to receive application forms.

(b) A separate application must be filed for each laboratory location. However, laboratories within a hospital that are located at the same street address and under common direction have the option of applying for a single certificate or multiple certificates for the laboratory sites within the same physical location or street address. In addition, not-for-profit or Federal, State, or local government laboratories that engage in limited public health testing (that is, few types of tests) may operate under one certificate. A laboratory that is not at a fixed location, that is, a laboratory that moves from testing site to testing site (such as health screening fairs) or other temporary testing location must file a single application using the address of its designated primary site. A separate certificate, which reflects the address of the designated primary site, is required for each mobile unit providing laboratory testing.

(c) An application for the issuance of a registration certificate, a certificate of waiver, or a certificate or certificate of accreditation applicable to one or more laboratory test procedures or examinations included in the specialties or subspecialties listed in § 493.643(d)(3) must be made to HHS or its designee on a form or forms prescribed by HHS and must be signed by the owner or authorized representative of the laboratory.

(d) The application must include information that describes the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory, including—

(1) The names of the test procedures and examinations performed and the total number of test procedures and examinations performed annually, excluding tests for quality control, quality assurance, and proficiency testing purposes;

(2) The methodologies for test procedures and examinations performed; and

(3) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory test procedures and examinations.

§ 493.618 Additional application requirements.

In submitting an application for a registration certificate, a certificate of waiver, certificate of accreditation, or a certificate, a laboratory must agree to the following:

(a) To make records available and submit reports to HHS as HHS may require.

(b) To permit inspections by HHS or its designee as specified in subpart Q of this part. (Certificate of waiver laboratories are not subject to routine inspections.)

(c) To treat proficiency testing samples in the same manner as it treats materials derived from the human body referred to it for laboratory examinations or other procedures in the ordinary course of business. (Certificate of waiver laboratories are not subject to proficiency testing requirements.)

(d) To provide HHS with satisfactory assurances, through an attestation statement, signed by the laboratory owner or authorized representative, that the laboratory will be operated in accordance with the requirements established by the Secretary under section 353 of the PHS Act.

§ 493.622 Appeals procedures.

(a) If HHS denies a laboratory's application for a registration certificate, certificate of waiver, certificate of accreditation, or certificate or limits the laboratory's certificate, HHS gives the laboratory a statement of the grounds on which the denial or limitation is based and an opportunity for an appeal, in accordance with the procedures set forth in part 498 of this chapter.

(b) If a laboratory that is seeking a registration certificate, certificate of waiver, certificate of accreditation, or certificate has its application denied or its certificate limited, it cannot operate as a laboratory under the PHS Act (or, in the case of a limitation, in the areas covered by the limitation) unless the denial or limitation is overturned at the conclusion of the administrative appeals process provided by part 498 of this chapter. (In addition, the laboratory is not eligible for payment under the Medicare or Medicaid programs or, in the case of a limitation, cannot receive Medicare or Medicaid payment for services in the limited areas.)

(c) Additional provisions relating to appeal rights are set forth in §§ 493.626(b), 493.633(b), and 493.634(b).

§ 493.626 Registration certificate.

(a) HHS or its designee initially issues a registration certificate or, if the laboratory meets the requirements, a certificate of waiver to each laboratory, provided that the laboratory meets the application requirements of §§ 493.614 and 493.618 and pays the applicable fee as specified in § 493.638. A registration certificate does not include specialties/subspecialties of service, except as noted in § 493.633, but authorizes the entity to conduct laboratory testing until a determination of the appropriate level of compliance can be made and the appropriate certificate issued. The registration certificate issued in accordance with § 493.633(a)(2) to a laboratory that has a certificate of waiver to allow the laboratory to add a service(s) not listed in the waived test category reflects only the added service(s) noted on the laboratory's application. A registration certificate issued under this section is valid for a period of not more than 2 years or until such time as an inspection to determine program compliance can be conducted or the laboratory demonstrates that it qualifies to receive a certificate of waiver or a certificate of accreditation, whichever is shorter. HHS reissues a registration certificate to any laboratory for which HHS or its designee has not had an opportunity to determine compliance.

(b) Prior to expiration of the registration certificate, HHS notifies the laboratory of the applicable requirements to obtain a certificate of accreditation or a certificate and the amounts of the fees for issuing these certificates and, if applicable, the amount of the fee for determination of compliance. HHS may suspend, revoke, or limit a laboratory's registration certificate for failure to comply with the applicable requirements and may deny the laboratory's application for the applicable certificate. HHS may also impose certain alternative sanctions. HHS provides the laboratory with a statement of the grounds on which the sanctions and denial are based, an opportunity to respond to the imposition of the sanctions, and an opportunity for appeal, in accordance with the procedures set forth in part 498 of this chapter. If the laboratory requests an

appeal of a suspension or revocation, it may keep its registration certificate until a decision is made by an Administrative Law Judge (ALJ), unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health. In cases where the registration certificate would expire, a registration certificate is reissued to authorize testing until a decision is made by an ALJ, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health. HHS may impose certain alternative sanctions prior to a hearing. (In addition, for laboratories receiving payment from the Medicare or Medicaid programs, such payments are suspended on the effective date specified in the notice to the laboratory of the denial of the application for the applicable certificate, even if there has been no appeal decision issued.)

(c) In the event of a non-compliance determination resulting in denial of a laboratory's application for a certificate of accreditation or certificate, HHS may suspend, revoke, or limit a laboratory's registration certificate. HHS may also impose certain alternative sanctions. HHS provides the laboratory with a statement of the grounds on which the sanctions and application denial are based and with an opportunity for an appeal, in accordance with the procedures set forth in part 498 of this chapter. If the laboratory requests an appeal of a suspension, revocation, or limitation, it may keep its registration certificate until a decision is made by an ALJ, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health. In cases where the registration certificate would expire, a registration certificate is reissued to authorize testing until a decision is made by an ALJ, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health. HHS may impose certain alternative sanctions prior to a hearing. (In addition, for laboratories receiving payment from the Medicare or Medicaid programs, such payments are suspended on the effective date specified in the notice to the laboratory of the denial of the application for the applicable certificate, even if there has been no appeals decision issued.)

§ 493.630 Certificate.

HHS or its designee issues a certificate to each laboratory, provided the laboratory has a registration certificate and meets the application requirements of §§ 493.614 and 493.618, pays the applicable fee as specified in § 493.638, and meets all other applicable requirements of this part. A certificate is valid for not more than 2 years.

§ 493.631 Certificate of waiver.

HHS or its designee issues a certificate of waiver to a laboratory if it performs only waived tests, provided the laboratory meets the application requirements of §§ 493.614 and 493.618, pays the applicable fee as specified in § 493.638, and meets all other applicable requirements of this part. A certificate of waiver is valid for not more than 2 years.

§ 493.632 Certificate of accreditation.

HHS or its designee issues a certificate to a laboratory accredited by an HHS-approved accreditation organization, provided the laboratory has a registration certificate and meets the application requirements of §§ 493.614 and 493.618, pays the applicable fee as specified in § 493.638, and meets all other applicable requirements of this part. A certificate of accreditation is valid for not more than 2 years.

§ 493.633 Applicability of certificate, certificate of waiver, and certificate of accreditation.

(a) The certificate of waiver issued is applicable to tests listed in the waived test category. The certificate or certificate of accreditation issued is applicable to those specialties and subspecialties of service offered by the laboratory in accordance with this part.

(1) A laboratory performing only waived tests may not perform any examination or procedure not listed in the waived test category until it has requested and HHS has issued to it a registration certificate that covers the additional examinations or procedures requested by the laboratory. The laboratory may continue to perform waived tests that are covered by the certificate of waiver already issued to the laboratory. The registration certificate is valid for 2 years or until a compliance determination can be conducted, whichever is shorter. After HHS or its designee determines compliance, HHS issues a certificate that includes the additional specialties or subspecialties for which compliance has been determined.

(2) A laboratory possessing a certificate must notify HHS or its designee within 6 months of any changes in methodologies for any test procedure or examination it performs and any additions or deletions of tests or examinations performed. If the laboratory adds testing in a specialty or subspeciality *not* listed on its certificate, HHS or its designee will determine compliance. After HHS or its designee determines compliance, a revised certificate is issued that includes the additional specialties or subspecialties for which compliance has been determined.

(3) A laboratory possessing a certificate of accreditation must notify its approved accreditation organization within 6 months of any changes in methodologies for any test procedure or examination it performs or any additions or deletions of tests or examinations performed so that appropriate actions can be taken by the accreditation organization and a revised certificate can be issued when appropriate.

(b) HHS may suspend, revoke, or limit a laboraoty's registration certificate and may impose certain alternative sanctions for failure to comply with the notice requirements of this section. HHS provides the laboratory with a statement of grounds on which the sanctions are based, an opportunity to respond to the imposition of the sanctions, and an opportunity for an appeal, in accordance with the procedures set forth in part 498 of this chapter. If the laboratory requests an appeal of a suspension, revocation, or limitation, it retains its certificate or a reissued certificate until a decision is made by an ALJ, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health. HHS may impose certain alternative sanctions prior to a hearing. In addition, for laboratories receiving payment from the Medicare or Medicaid programs, such payments are suspended during the pendency of any hearing for failure to comply with the requirements of this part.

§ 493.634 Notification of changes.

(a) A laboratory must notify HHS or its designee within 30 days if changes occur in—

(1) Ownership;

(2) Name;

(3) Location;

(4) Director; or

(5) Supervisor (only applicable for a high complexity laboratory).

(b) HHS may suspend, revoke, or limit a laboratory's registration certificate, certificate of waiver, or certificate of accreditation or may impose certain alternative sanctions for failure to comply with the notice requirements of this section. In such an event, HHS provides the laboratory with a statement of grounds on which the sanction is based and an opportunity for an appeal, in accordance with the procedures set forth in part 498 of this

chapter. If the laboratory requests an appeal of a suspension, revocation, or limitation, it retains its certificate or a reissued certificate until a decision is made by an ALJ, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health. (In addition, for laboratories participating in Medicare or Medicaid, payments are suspended during the pendency of any hearing for failure to comply with the notice requirements.)

(c) If a revised certificate is necessary because of the changes identified in paragraph (a) of this section, the laboratory must pay the fee for a revised certificate as required in § 493.639

§ 493.638 Registration certificate and certificate fees.

(a) *Basic rule.* Laboratories must pay a fee for the issuance of a registration certificate, certificate of waiver, certificate of accreditation, or a certificate, as applicable. Laboratories must also pay a fee to reapply for a certificate of waiver, certificate of accreditation, or a certificate. The total of fees collected by HHS under the laboratory program must be sufficient to cover the general costs of administering the laboratory certification program under section 353 of the PHS Act. For registration certificates and certificates, this includes evaluating and monitoring proficiency testing programs and accreditation bodies and implementing, monitoring, and enforcing compliance with section 353 of the PHS Act and collection of fees and issuing registration certificates and certificates. For a certificate of waiver, this includes the cost of issuing the certificate of waiver, collection of fees and the administrative costs associated with evaluating tests to determine if a certificate of waiver should be issued. For a certificate of accreditation this includes the cost of issuing the certificate of accreditation, collection of fees and the administrative costs associated with evaluating programs of accrediting bodies and the costs to conduct sample validation surveys of accredited laboratories.

(b) *Fee amount.* The fee amount is set annually by HHS on a calendar year basis and is based on schedules, or ranges, of laboratory test volume (excluding tests performed for quality control, quality assurance, and proficiency testing purposes) and scope of specialties tested, with the amounts of the fees in each schedule a function of the costs for all aspects of general administration of CLIA as set forth in §§ 493.649 (b) and (c). This fee is assessed and payable at least biennially. The methodology used to determine the amount of the fee is found in § 493.649. The amount of the fee applicable to the issuance of the registration certificate or the issuance or renewal of the certificate of waiver, certificate of accreditation, or certificate is the amount in effect at the time the application is received. Upon receipt of an application for a registration certificate, certificate of waiver, certificate of accreditation, or certificate, HHS or its designee notifies the laboratory of the amount of the required fee. The amount of the fee is based on whether the laboratory is considered small, medium, or large (based on the volume and scope of testing performed by the laboratory).

§ 493.639 Fee for revised certificate.

(a) If, after a laboratory is issued a registration certificate, it changes its name or location, the laboratory must pay a fee to cover the cost of issuing a revised registration certificate. The fee for the revised registration certificate is based on the cost to issue the revised certificate to the laboratory.

(b) A laboratory must pay a fee to cover the cost of issuing a revised certificate in any of the circumstances specified in paragraphs (b) (1) and (2). The fee for issuing an appropriate revised certificate is based on the cost to issue the revised certificate to the laboratory. (An additional fee is also required under § 493.643(e) if it is necessary to determine compliance with additional requirements and, if a laboratory with a certificate of waiver wishes to perform tests not listed in the waived test category, it must, as set forth in § 493.626, pay an additional fee for a registration certificate to cover the new testing.)

(1) If after a certificate, certificate of accreditation, or certificate of waiver is issued, a laboratory changes its name, location, or its director;

(2) If after a certificate or certificate of waiver is issued, a laboratory deletes services or wishes to add services and requests that its certificate be upgraded or that its certificate of waiver be changed or eliminated.

§ 493.643 Fee for determination of program compliance.

(a) *Fee requirement.* In addition to the fee required under § 493.638, laboratories regulated subject to the requirements of this part must pay a fee to cover the cost of determining program compliance, unless it is issued a certificate of waiver or a certificate of accreditation.

(b) *Costs included in the fee.* Included in the fee for determining program compliance is the cost of evaluating qualifications of personnel; monitoring proficiency testing; conducting onsite inspections; documenting deficiencies; evaluating laboratories' plans to correct deficiencies; and necessary administrative costs. HHS sets the fee amounts annually on a calendar year basis. Laboratories are inspected biennially; therefore, fees are assessed and payable biennially. If additional expenses are incurred to conduct follow up visits to verify correction of deficiencies, to impose sanctions, and/or for surveyor preparation for and attendance at ALJ hearings, HHS assesses an additional fee to include these costs. The additional fee is based on the actual resources and time necessary to perform the activities.

(c) *Classification of laboratories that require inspection for purpose of determining amount of fee.* (1) There are ten classifications (schedules) of laboratories for the purpose of determining the fee amount a laboratory is assessed. Each laboratory is placed into one of the ten following schedules based on the laboratory's scope and volume of testing (excluding tests performed for quality control, quality assurance, and proficiency testing purposes).

(i) (A) *Schedule A Low Volume.* The laboratory performs not more than 2,000 laboratory tests annually.

(B) *Schedule A.* The laboratory performs tests in no more than 3 specialties of service with a total annual volume of more than 2,000 but not more than 10,000 laboratory tests.

(ii) *Schedule B.* The laboratory performs tests in at least 4 specialties of service with a total annual volume of not more than 10,000 laboratory tests.

(iii) *Schedule C.* The laboratory performs tests in no more 3 specialties of service with a total annual volume of more than 10,000 but not more than 25,000 laboratory tests.

(iv) *Schedule D.* The laboratory performs tests in at least 4 specialties with a total annual volume of more than 10,000 but not more than 25,000 laboratory tests.

(v) *Schedule E.* The laboratory performs more than 25,000 but not more than 50,000 laboratory tests annually.

(vi) *Schedule F.* The laboratory performs more than 50,000 but not more than 75,000 laboratory tests annually.

(vii) *Schedule G.* The laboratory performs more than 75,000 but not more than 100,000 laboratory tests annually.

(viii) *Schedule H.* The laboratory performs more than 100,000 but not more than 500,000 laboratory tests annually.

(ix) *Schedule I.* The laboratory performs more than 500,000 but not more than 1,000,000 laboratory tests annually.

(x) *Schedule J.* The laboratory performs more than 1,000,000 laboratory tests annually.

(2) For purposes of determining a laboratory's classification under this section, a test is a procedure or examination for a single analyte. (Tests performed for quality control, quality assurance, and proficiency testing are excluded from the laboratory's total annual volume). Each profile (that is, group of tests) is counted as the number of separate procedures or examinations; for example, a chemistry profile consisting of 18 tests is counted as 18 separate procedures or tests.

(3) For purposes of determining a laboratory's classification under this section, the specialties and subspecialties of service for inclusion are:

(i) The specialty of Microbiology, which includes one or more of the following subspecialties:

(A) Bacteriology.
(B) Mycobacteriology.
(C) Mycology.
(D) Parasitology.
(E) Virology.

(ii) The specialty of Serology, which includes one or more of the following subspecialties:

(A) Syphilis Serology.
(B) General immunology

(iii) The specialty of Chemistry, which includes one or more of the following subspecialties:

(A) Routine chemistry.
(B) Endocrinology.
(C) Toxicology.
(D) Urinalysis.

(iv) The specialty of Hematology.

(v) The specialty of Immunohematology, which includes one or more of the following subspecialties:

(A) ABO grouping and Rh typing.
(B) Unexpected antibody detection.
(C) Compatibility testing.
(D) Unexpected antibody identification.

(vi) The specialty of Pathology, which includes the following subspecialties:

(A) Cytology.
(B) Histopathology.
(C) Oral pathology.

(vii) The specialty of Radiobioassay.

(viii) The specialty of Histocompatibility.

(ix) The specialty of Cytogenetics.

(d) *Additional fees.* (1) If after a certificate or certificate of waiver is issued a laboratory adds services and requests that its certificate be upgraded, the laboratory must pay an additional fee if, in order to determine compliance with additional requirements, it is necessary to conduct an inspection, evaluate personnel, or monitor proficiency testing performance. The additional fee is based on the actual resources and time necessary to perform the activities. HHS revokes the laboratory's certificate for failure to pay the compliance determination fee.

(2) If it is necessary to conduct a complaint investigation, impose sanctions or conduct a hearing, HHS assesses the laboratory, other than a State-exempt laboratory, a fee to cover the cost of these activities. If a complaint investigation results in a complaint being unsubstantiated, or if an HHS adverse action is overturned at the conclusion of the administrative appeals process, the government's costs of these activities are not imposed upon the laboratory. Costs for these activities are based on the actual resources and time necessary to perform the activities and are not assessed until after the laboratory concedes the existence of deficiencies or an ALJ rules in favor of HHS. HHS revokes the laboratory's certificate for failure to pay the assessed costs.

§ 493.645 Fee(s) applicable to accredited laboratories/approved State licensure programs.

(a) *Accredited laboratories.* (1) In addition to the certificate fee, a laboratory that is issued a certificate of accreditation is also assessed a fee to cover the cost of evaluating individual laboratories to determine overall whether an accreditation organization's standards and inspection policies are equivalent to the Federal program. All accredited laboratories share in the cost of these inspections. These costs are the same as those that are incurred when inspecting nonaccredited laboratories.

(2) If, in the case of a laboratory that has been issued a certificate of accreditation, it is necessary to conduct a complaint investigation, impose sanctions, or conduct a hearing, HHS assesses that laboratory a fee to cover the cost of these activities. If a complaint investigation results in a complaint being unsubstantiated, or if an HHS adverse action is overturned at the conclusion of the administrative appeals process, the cost of these activities are not imposed upon the laboratory. Costs are based on the actual resources and time necessary to perform the activities and are not assessed until after the laboratory concedes the existence of deficiencies or an ALJ rules in favor of HHS. HHS revokes the laboratory's certificate for failure to pay the assessed costs.

(3) If, in the case of a laboratory subject to an inspection under paragraph (a), followup visits are necessary because of identified deficiencies, HHS assesses the laboratory a fee to cover the cost of these visits. The fee is based on the actual resources and time necessary to perform the followup visits. HHS revokes the laboratory's certificate of accreditation for failure to pay the assessed fee.

(b) *Approved State licensure programs.* State licensure programs approved by HHS are assessed a fee for the following:

(1) Costs of Federal inspections of laboratories in that State (that is, State-exempt laboratories) to verify that standards are being enforced in an appropriate manner.

(2) Costs incurred for investigations of complaints against the State's State-exempt laboratories if the complaint is substantiated.

(3) Costs of the State's prorata share of general overhead to develop and implement CLIA.

§ 493.646 Payment of fees.

(a) Except for State-exempt laboratories, all laboratories are notified in writing by HHS or its designee of the appropriate fee(s) and instructions for submitting the fee(s), including the due date for payment and where to make payment. Registration certificates, certificates of waiver, certificates of accreditation, or certificates are not issued until the applicable fees have been paid.

(b) For State-exempt laboratories, HHS estimates the cost of conducting validation surveys within the State for a 2-year period. HHS or its designee notifies the State by mail of the appropriate fees, including the due date for payment and the address of the United States Department of Treasury designated commercial bank to which payment must be made. In addition, if complaint investigations are conducted in laboratories within these States and are substantiated, HHS bills the State(s) the costs of the complaint investigations.

§ 493.649 Methodology for determining fee amount.

(a) *General rule.* The amount of the fee in each schedule for compliance determination surveys is based on the average hourly rate (which includes the costs to perform the required activities and necessary administration costs) multiplied by the average number of hours required, or if activities are performed by more than one of the entities listed in paragraph (b) of this section, the sum of the products of the applicable hourly rates multiplied by the

average number of hours required by the entity to perform the activity. The fee for issuance of the registration certificate or certificate is based on the laboratory's scope and volume of testing.

(b) *Determining average hourly rates used in fee schedules.* Three different entities perform activities related to the issuance or reissuance of certificates of waiver, certificates of accreditation, or certificates and determining program compliance. HHS determines the average hourly rates for the activities of each of these entities.

(1) *State survey agencies.* The following costs are included in determining an average hourly rate for the activities performed by State survey agencies:

(i) The costs incurred by the State survey agencies in evaluating personnel qualifications and monitoring each laboratory's participation in an approved proficiency testing program. The cost of onsite inspections and monitoring activities is the hourly rate derived as a result of an annual budget negotiation process with each State. The hourly rate encompasses salary costs (as determined by each State's civil service pay scale) and fringe benefit costs to support the required number of State inspectors, management and direct support staff.

(ii) Travel costs necessary to comply with each State's administrative requirements and other direct costs such as equipment, printing, and supplies. These costs are established based on historical State requirements.

(iii) Indirect costs as negotiated by HHS.

(2) *Federal agencies.* The hourly rate for activities performed by Federal agencies is the most recent average hourly cost to HHS to staff and support a full time equivalent employee. Included in this cost are salary and fringe benefit costs, necessary administrative costs, such as printing, training, postage, express mail, supplies, equipment, computer system and building service charges associated with support services provided by organizational components such as a computer center, and any other oversight activities necessary to support the program.

(3) *HHS contractors.* The hourly rate for activities performed by HHS contractors is the average hourly rate established for contractor assistance based on an independent government cost estimate for the required workload. This rate includes the cost of contractor support to provide proficiency testing programs to laboratories that do not participate in an approved proficiency testing program, provide specialized assistance in the evaluation of laboratory performance in an approved proficiency testing program, perform assessments of cytology testing laboratories, conduct special studies, bill and collect fees, issue certificates, establish accounting, monitoring and reporting systems, and assist with necessary surveyor training.

(c) *Determining number of hours.* The average number of hours used to determine the overall fee in each schedule is HHS's estimate, based on historical experience, of the average time needed by each entity to perform the activities for which it is responsible.

(Catalog of Federal Domestic Assistance Program No. 13.714, Medical Assistance Program; No. 13.773, Medicare—Hospital Insurance; and No. 113.774, Medicare-Supplementary Medical Insurance)

Dated: December 1, 1991.

Gail R. Wilensky,

Administrator, Health Care Financing Administration.

Approved: January 23, 1992.

Louis W. Sullivan,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 493

[HSQ–179–F]

RIN 0938–AE60

Medicare Program; Medicare and Laboratory Certification Program; Enforcement Procedures for Laboratories

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: These regulations set forth the rules for sanctions that HCFA may impose on laboratories that are found not to meet Federal requirements. These include the principal sanctions of suspending, limiting, or revoking the laboratory's certificate issued under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), and cancelling the laboratory's approval to receive Medicare payment for its services, and the alternative sanctions that may be imposed instead of or before the principal sanctions.

These amendments are necessary to conform HCFA regulations to changes made in the law by the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) and the 1988 amendments to section 353 of the Public Health Service Act (PHS Act). The latter are commonly referred to as "CLIA 88".

The purpose of the amendments is to ensure that functioning laboratories are capable of providing accurate and reliable test results and that the health of individuals served by the laboratory and that of the general public is not adversely affected by laboratory operations and by testing procedures that do not meet the standards set forth in other subparts of part 493 of the HCFA regulations.

DATES: *Effective date:* These regulations are effective September 1, 1992.

ADDRESSES: *Copies:* To order copies of the **Federal Register** containing this document, send your request to the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402–9325. Specify the date of the issue requested and stock number 069–001–00042–4. Enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 783–3238 or by faxing to (202) 275–6802. The cost for each copy (in paper or microfiche form) is $1.50. In addition, you may view and photocopy the **Federal Register** document at most libraries designated as U.S. Government Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register.** The order desk operator will be able to tell you the location of the U.S. Government Depository Library nearest to you.

FOR FURTHER INFORMATION CONTACT: Irene Gibson (410) 966–6768.

SUPPLEMENTARY INFORMATION:

I. Background

A. Changes in the Laws

Before enactment of the laws cited above under "Summary", there were two sets of regulations and two survey and enforcement systems applicable to laboratories. HCFA was responsible for the determination of whether a laboratory met the requirements to be approved to receive Medicare payment for its services. The Public Health Service was responsible for the Federal licensure of laboratories that engaged in interstate commerce.

The only sanctions available under these two systems, for a laboratory that did not meet the Federal requirements, was the denial or cancellation of the approval to receive Medicare payment, and the suspension, revocation or

limitation of the license to engage in interstate commerce.

Section 4064(d) of OBRA '87 added to the Act a new section 1846 which directs the Secretary to develop and implement a range of intermediate sanctions to apply to laboratories that receive Medicare payments. These sanctions must include—

(1) Directed plans of correction;

(2) Civil money penalties;

(3) Payment for the costs of onsite monitoring by the agency responsible for conducting certification inspections; and

(4) Suspension of all or part of the payments to which the laboratory would otherwise be entitled for services furnished after the effective date of sanction. The Secretary is also required to develop and implement specific procedures with respect to how and when each of the sanctions is to be imposed, and the amount of any penalties. The procedures must be designed to minimize the time lapse between identification of the violations and imposition of the sanctions, and provide for incremental more severe penalties for repeated or uncorrected deficiencies.

The primary purpose of the "CLIA 88" amendments is to strengthen the Federal oversight of laboratories in order to ensure that test results are accurate and reliable.

The new law creates a national, unified enforcement mechanism that affects virtually every laboratory in the country, not just those that are involved in interstate commerce. Every laboratory subject to the statute's broad definition will not be subject to CLIA 88 requirements and, because enforcement comes under the jurisdiction of the Secretary, every laboratory will be subject to regulations promulgated by the Secretary, regardless of whether it participates in Medicare. Under CLIA 88 it is no longer necessary to have separate sets of Federal rules to implement the two statutes. Moreover, section 6141 of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239) revoked the exemption of low-volume physician office laboratories from the CLIA certification requirements, and requires all laboratories that participate in Medicare to meet the CLIA 88 requirements. Since it is now possible to have one consolidated set of Federal requirements under a single enforcement system, it will no longer be possible for a laboratory to be sanctioned under one law, while escaping sanction under the other. In order to continue to operate under CLIA 88 all laboratories subject to the law must be inspected under CLIA 88 to obtain a CLIA certificate, with the exception of laboratories that request and receive a certificate of waiver. These laboratories are not inspected unless: a complaint that warrants an inspection is received; HCFA has reason to believe the laboratory is being operated in a manner that constitutes a risk to human health; on a random sample basis; to determine whether the laboratory is performing tests not listed in § 493.15; or to collect information for the addition, deletion or continued inclusion of specific waivered tests.

CLIA 88 grants the Secretary new and more flexible enforcement authority, including the use of intermediate sanctions and civil action to enjoin a laboratory from continuing an activity that constitutes a significant hazard to the public health. The amended law also—

- Provides for incarceration and fines for any person convicted for intentionally violating any CLIA requirements;
- Provides for administrative and judicial review procedures available to a laboratory when an intermediate sanction is imposed or its CLIA certificate is suspended, revoked, or limited; and
- Requires the Secretary to publish annually a list of all the laboratories against which a sanction has been imposed or legal action has been taken.

To safeguard against errors in the names of laboratories or individuals cited in the annual laboratory registry publication, we will send to each HCFA regional office its portion of the laboratory registry for verification of information before publication. This procedure will prevent the serious injury to a provider's or individual's professional reputation and problems that could result from inaccurate reporting.

Under previous CLIA rules, licenses were issued annually to laboratories based on the specialties and subspecialties of tests for which the laboratory could demonstrate compliance with Federal quality standards. Under CLIA 88, CLIA certificates will be issued for a two-year period but may be suspended or limited prior to a hearing in cases of noncompliance which pose immediate jeopardy to patients or the general public. In such cases, CLIA certificates can be revoked following a hearing. In cases that do not pose immediate jeopardy, in lieu of suspension, limitation, or revocation of the CLIA certificate, HCFA may impose alternative sanctions after providing the laboratory an opportunity to respond to the sanction and request a hearing.

B. Consolidation of Previous Rules

On March 14, 1990, we published (at 55 FR 29538) a final rule with comment period to consolidate the previous Medicare and CLIA regulations discussed above and designate them under a new part 493-Laboratory Requirements. The requirements of part 493 were effective as of September 10, 1990 except for subpart H—Participation in Proficiency Testing, which was effective as of January 1, 1991. The requirements of part 493 will apply to virtually all laboratories and will be used to determine whether a laboratory may continue to operate and whether its services qualify for Medicare payment.

These rules amend the new Part 493 to add a Subpart R—Enforcement Procedures. The impact of these changes on the programs is discussed below.

II. Program Impact

A. Medicare and Medicaid

Under section 1846 of the Act, Medicare payment for laboratory services may continue for up to 1 year after condition level deficiencies (noncompliance with any of the conditions that a laboratory must meet in order to obtain a CLIA certificate) have been identified as long as one or more intermediate sanctions are being imposed. Because section 1846 permits HCFA to develop and implement alternative sanctions of graduated severity according to levels of severity of deficiencies, we have established three levels of noncompliance:

- Condition level deficiencies with immediate jeopardy.
- Condition level deficiencies without immediate jeopardy.
- Deficiencies below the condition level without immediate jeopardy.

Condition level deficiencies that pose immediate jeopardy to the health and safety of individuals served by the laboratory or that of the general public will result in very swift cancellation of Medicare approval if the jeopardy is not removed immediately.

On the other hand, condition level deficiencies that do not pose immediate jeopardy no longer need trigger immediate cancellation of Medicare approval. While cancellation of approval would always remain an option, other measures may be employed first, while corrections are being made, in an effort to encourage laboratories to achieve compliance in a timely manner. However, condition level deficiencies that remain uncorrected after a reasonable period of time will still lead to cancellation of approval of

Medicare payment for the laboratory's services.

Section 1902(a)(9)(C) of the Act provides that payment for laboratory services may be made under the Medicaid State plan only if the services are furnished by a laboratory that meets CLIA requirements.

B. CLIA 88

The major program impacts of the CLIA 88 amendments—the extension of CLIA requirements to all laboratories that test human specimens for health purposes, and the opportunity to integrate the previously separate inspection and enforcement systems—have been discussed above under Background. Since the CLIA inspection and enforcement provisions are essentially the same as those set forth in the Medicare statute or in section 1846 of the Social Security Act, we believe that we should impose sanctions under CLIA based on the same levels of noncompliance as under the Medicare statute.

C. Unsuccessful Participation in Proficiency Testing

The CLIA 88 amendments require that laboratories issued a CLIA certificate must participate in an approved proficiency testing program. Laboratories which had been previously regulated under Medicare or CLIA are required to continue to participate in proficiency testing under CLIA 88. Previously unregulated laboratories will be required to begin proficiency testing in 1994. Subpart H of 42 CFR Part 493, included as part of another final CLIA regulation with comment period published elsewhere in this issue of the **Federal Register**, specifies that any laboratory which performs tests of moderate or high complexity, or both, must enroll in a proficiency testing program for each of the specialties, subspecialties, and analytes authorized by its CLIA certificate. Subpart H sets forth successful participation in proficiency testing as a condition level requirement. As stated in this regulation at § 493.1804(b)(2), HCFA may impose alternative or principal sanctions against any laboratory with condition level deficiencies. Therefore, laboratories which do not participate successfully in proficiency testing will be subject to the same sanctions that are applicable for noncompliance with any other CLIA condition. Additionally, if any laboratory fails to participate successfully in proficiency testing, HCFA may impose the training and technical assistance provisions set forth at § 493.1838 of the regulation.

D. Phased-in Imposition of Alternative Sanctions for Unsuccessful Participation in Proficiency Testing

In order to provide adequate opportunity for all laboratories to fully understand the PT system under CLIA prior to being sanctioned for unsuccessful participation in PT, we will phase in the enforcement of PT requirements. The authority for this phase-in is based on sections 1846 of the Social Security Act and 353(h) of the Public Health Service Act. These statutory sections provide the Secretary with the opportunity to develop and implement procedures with respect to when and how intermediate sanctions are to be imposed against laboratories. Under CLIA, previously regulated laboratories are subject to PT requirements as of the effective date of all CLIA requirements, published elsewhere in this issue of the **Federal Register**. Previously unregulated laboratories will not be required to meet PT requirements until January 1, 1994. In both cases, however, the first citation of unsuccessful PT participation will not result in the imposition of a sanction. Unsuccessful participation in subsequent PT events will result in the imposition of a sanction. This policy will afford the laboratory a longer period of time to correct its deficiencies than will otherwise be the case for subsequent PT events. We developed this approach in order to provide all laboratories additional time to understand the PT requirements with which they may be unfamiliar and with which they may be initially found to be noncompliant, as well as to enable laboratories to grasp fully the sanctions which may be imposed for unsuccessful PT participation. As always, however, the Secretary will take any action that may be necessary in cases of immediate jeopardy. This could include the imposition of sanctions for the first time occurrence of unsuccessful PT participation in those instances where the Secretary determines that such unsuccessful PT participation itself poses an immediate jeopardy situation or demonstrates the existence of an immediate jeopardy situation. Without such a policy, we would be required to enforce immediately the revised PT requirements published elsewhere in this issue of the **Federal Register** (and designated as HSQ–176–FC). We would also be required to impose sanctions for noncompliance with PT requirements with which the laboratory industry is unfamiliar.

E. Phased-in Imposition of Alternative Sanctions for Noncompliance With Other Conditions

For laboratories which were not previously regulated under CLIA or Medicare, HCFA will also phase in the imposition of intermediate sanctions for noncompliance with CLIA conditions other than PT. Under this system, which is intended to be separate from the phase-in of intermediate sanctions for the unsuccessful participation in PT as described above, intermediate sanctions will not be imposed during a laboratory's first inspection cycle against applicable CLIA requirements, if the laboratory's deficiencies do not pose immediate jeopardy. However, the laboratory will be required to correct its deficiencies in the areas specified by HCFA over a longer period of time than will otherwise be the case for noncompliance identified in all subsequent CLIA inspections. We developed this phase-in of alternative sanctions for newly regulated laboratories to provide additional time for them to understand the CLIA conditions with which they are found to be noncompliant upon their initial inspection.

The use of this phased-in system for the imposition of sanctions should mitigate the full impact of the misunderstanding that may be unavoidable—even with our planned educational activity, when dealing with a large number of small laboratory operations that have never previously been subject to any governmental onsite inspections. This will protect against disruption of services in laboratories that are attempting in good faith to comply with the new CLIA requirements. At the same time, it will provide for use of the statutory sanctions where an immediate jeopardy situation is identified.

For those laboratories that have been subject to regulation by the Federal government through CLIA '67, Medicare or Medicaid, we intend to have all CLIA and Medicare sanctions available after the effective date of these regulations. First, these laboratories have been accustomed to the inspection process and, notwithstanding the change in substantive Federal requirements that CLIA represents, the inspection process itself will remain largely unchanged. Thus, there is no need here, as there is for newly regulated laboratories, to allow time for currently regulated laboratories to familiarize themselves with the interplay of inspections, the need for the correction of deficiencies, and the possibility of sanctions should

compliance not be achieved. Second, the Congress was clearly interested in having the enforcement provisions of CLIA become effective at the earliest possible date after CLIA was enacted. To enable laboratories that have been consistently subject to sanctions for noncompliant practices to evade enforcement, would not be consistent with this Congressional intent and would needlessly increase the potential for a reduction in reliable and accurate laboratory testing.

III. Notice of Proposed Rulemaking

On April 2, 1991, at 56 FR 13430, we published a proposed rule (identified as HSQ–179–P) setting forth the enforcement procedures for laboratories, and provided 60 days for public comment.

In this section of the preamble, we discuss the comments received in response to the April 2 proposed rule, our responses to those comments, and changes made in the proposed policies.

A. Definitions (section 493.1801)

Section 493.1801 defined the following terms: "CLIA certificate", "provisional certificate", "condition level requirement" and "condition level deficiency", "HCFA agent", "Immediate jeopardy", and "Lower level deficiency".

1. *Comment:* Several commenters recommended that the final regulation include definitions of "owner" and "operator" as referred to in § 493.1840 because without a definition accountability cannot be placed. In addition, one commenter wanted to know if owner or operator was limited to a person because that party believes "person" also means corporations, partnerships, etc. Other commenters wanted to know if stockholders of publicly held laboratories would be considered owners.

Response: We have added definitions of those two terms in § 493.2 of the final rule. In summary, we have stated that an operator means the individual or group of individuals who oversee the operation of a laboratory and who bear primary responsibility for the safety and reliability of laboratory testing, while an owner means an individual who owns an interest in the laboratory.

2. *Comment:* Several commenters want condition level deficiency and lower level deficiency to be more clearly delineated. They were also unclear about the relationship between "elements", "standards" and "conditions".

Response: A condition level deficiency is a deficiency with respect to any of the conditions that a laboratory must meet in order to obtain a CLIA certificate. A deficiency not at the condition level is a deficiency with respect to one or more of the standard level requirements that are below the condition level, and, therefore, are not identified as conditions. These requirements may appear in this part under the heading "standard" or under no heading, and are what is meant by "lower level" requirements. There is no official requirement category designated "element" in this part. We have expanded the definition of "condition-level deficiency" in the final rule.

3. *Comment:* Several commenters questioned what entities (other than State survey agencies) HCFA might use as agents.

Response: We have listed other entities which HCFA might use as its agents in the definition of HCFA agent at § 493.2.

4. We received single requests for definitions of each of the following terms:

a. *"Significant hazard to the public health".* This means a deficiency that may cause harm to members of the community who are not necessarily patients served directly by the laboratory (for example, incorrect reporting of accurate test results with respect to communicable diseases). It is equivalent to "immediate jeopardy" for patients served by the laboratory and has been incorporated in the definition of the latter term.

b. *"Repeat deficiencies".* (To explain the number of occurrences necessary for it to be considered a "repeat" deficiency.) We have revised the statements in § 493.1804(d)(1)(iii), § 493.1828(a)(2)(i)(B) and § 493.1834(d)(1)(ii) to make clear that reference is to the "same" deficiency found in three consecutive inspections.

c. *"Intentional violation".* We have added a definition of this term in the final rule, which states that an intentional violation means knowing and willful noncompliance with any CLIA condition.

d. *"Cancellation of Medicare approval."* Cancellation of a laboratory's Medicare approval means that Medicare payment for the laboratory's services will not be made after the effective date of cancellation and the laboratory's Medicare participation has, therefore, been canceled.

e. *"Directed plan of correction".* This is explained in § 493.1832.

f. *"Laboratory".* This term is defined in § 493.2, which contains definitions applicable to all of part 493.

B. Imposition of Sanctions (Sections 493.1806—493.1842)

Commenters were concerned both with the effect of sanctions on laboratories, and with the procedures for imposing the sanctions.

1. *Comment:* 32 commenters were concerned that sanctions could lead to closure or to limitations of voluntary testing in many small laboratories such as those in physicians' offices.

Response: It is true that sanctions imposed upon small laboratories, including those in physicians' offices, may lead to closure or to limitations on the types of tests done. However, our objective under CLIA is to develop regulations that provide an appropriate balance between the concern for access to care and the need to protect the public from inaccurate and potentially dangerous test results.

2. *Comment:* 25 commenters indicated their concern that these regulations could limit access to or delay laboratory testing for patients.

Response: It is true that if a laboratory is unable to perform certain tests because it was found to be out of compliance with CLIA requirements, this could possibly limit access. Individuals who require those tests may have to wait longer for the results since those tests would have to be done elsewhere. It is generally in the patient's better interest to wait a little longer for test results which are accurate and reliable. Once the noncomplying laboratory has come into compliance and the alternative sanction or limitation of certificate is lifted, access to that laboratory will be restored.

3. *Comment:* Ten commenters were concerned that these regulations would create a great hardship on the elderly who, if their physicians' labs are sanctioned, would have to travel farther to have tests done and wait longer for results. The recommendation was that physicians' office laboratories (POLs) be exempted from CLIA requirements as a way to avoid this problem.

Response: We have no authority to exempt physicians' office laboratories from CLIA requirements. However, the plan for implementation of CLIA requirements includes a gradual phase-in both as to dates when certain conditions must be met, and the date when we will begin to impose sanctions for failure to comply with those conditions, if the failure to comply with those conditions does not pose immediate jeopardy.

4. *Comment:* Several commenters indicated their concern that sanctions would raise the cost of laboratory

testing and medical care in general, and would create significant paperwork burdens.

Response: In the preamble to the proposed rule, under "V. Regulatory Impact Analysis," we explained that this rule could have some potential to have significant impact on some laboratories. However, we have since determined that this rule will not have a significant impact in the form of increased costs of laboratory testing and medical care. In fact, any substantial impact that results from the implementation of CLIA requirements will be due to the CLIA conditions set forth in the regulations published elsewhere in this edition of the Federal Register and designated as HSQ–176–FC. Any significant impact would be reflected in the form of the increased costs of upgrading laboratories to meet CLIA requirements, and not the costs associated with being sanctioned. Moreover, both the requirements a laboratory must meet to obtain any type of CLIA certificate, and the Secretary's obligation to impose enforcement sanctions are mandated by the law and must be implemented, regardless of the possibility that costs will rise. This rule does not impose a significant paperwork burden. It does contain some information collection requirements, and we have requested approval of these requirements.

5. Comment: Four commenters had concern regarding the impact of CLIA on the States. One commenter indicated that because of the additional work involved (monitoring, imposing sanctions, follow-up visits, notifying clients when laboratories are sanctioned and when the sanctions are rescinded), a "tremendous burden" will be added to the States' workload. This commenter would prefer to publish notices of sanctions and recission of sanctions in the local newspapers. Another commenter disagrees with the section on "Federalism" within the Regulatory Impact Analysis, which states that there will be "little of the former role for States in laboratory regulation remaining under CLIA 88". The same commenter feels the States will develop, in time, programs more stringent than those required by CLIA. The same commenter would prefer that States continue to have a substantial role in laboratory regulation, rather than defer to the proposed Federal program and diminish their roles in protecting the public health and the safety of their citizens. The third commenter would like a clearer understanding of States' roles in the enforcement process. The last commenter also stated that there will be little of the former role for States remaining under CLIA 88. He suggested that the Federal government has not been effective in preventing deaths in its own Health and Human Services/Public Health Services/IHS system and indicated that the States should not lightly allow HCFA to usurp their authority in this area.

Response: It is true that the role of the States will significantly change as a result of section 1846 of the Social Security Act, section 353 of the Public Health Service Act, and implementing regulations. We explained this in the Preamble to the proposed regulations under the section headed B. Executive Order 12612. In response to the recommendation that the States not defer to the proposed Federal program and diminish their roles, we will acknowledge in a separate regulation the States' right to apply for HCFA approval of their licensure programs so that laboratories licensed in those States would be exempt from CLIA requirements. The term "State-exempt" in the final rule refers to laboratories in States with licensure programs that have requirements equal to or more stringent than the Federal requirements and that have been approved by HCFA. As for its role in the enforcement process, the State will still be responsible for inspecting laboratories for compliance with CLIA requirements even if that State's licensure program is not approved by HCFA as a basis for exemption from CLIA requirements. The State will recommend enforcement action to HCFA and may notify laboratories of the types of adverse actions that HCFA may impose. There are many more specific functions in addition to these general ones.

6. Comment: Four commenters were of the opinion that the imposition of sanctions would be tantamount to interference with medical practice. One stated that CLIA 88 is a further Federal government encroachment into the field of medicine that will not improve care but will severely decrease access to care for patients. One physician wrote that the premise that the health of patients is being threatened by laboratories in physicians' offices is nonsense and that closing such laboratories will have a negative impact on overall health care. For example: if tests are sent to bigger laboratories, another step will be added to the diagnostic process which will delay obtaining of test result by both rural and urban physicians who frequently need laboratory results immediately. This commenter feels that automation and technology have advanced to the extent that smaller laboratories can perform many simple tests just as easily and more reasonably and efficiently than "big" laboratories. Another commenter stated that the intrusion of HCFA into physicians' office laboratories deteriorates the doctor/patient relationship and creates interference when quick results are necessary.

Response: We disagree with these commenters, although we understand that the new CLIA regulations may to some extent, interfere in the autonomy of physicians if their laboratories are not in compliance with Federal requirements. However, Congress has mandated that we regulate laboratory practices no matter how small the laboratory, and directed us to use various enforcement remedies when deficiencies are identified. If cancellation of Medicare approval and revocation of CLIA certificates become necessary, then disadvantages of delays caused by submission of specimens to other laboratories are offset by the advantages of accurate testing. Despite the technological advances that have enabled physician's office laboratories to perform tests easily, the possibility of errors still exists, and the consequences of errors could be dangerous, despite the simplicity of the tests.

7. Comment: Five commenters were of the opinion that the additional recordkeeping requirements mandated by CLIA would be burdensome and might not be provided in a timely manner, thereby distorting the integrity of the information. They all seem to agree that in order to meet the paperwork requirements, they will require additional funds from HCFA.

Response: The response to this comment is located in the Regulatory Impact Analysis of HSQ–176–FC, published elsewhere in this issue of the Federal Register.

8. Comment: 14 commenters expressed the opinion that CLIA in general should either be repealed or further reviewed by Congress.

Response: This comment is outside the purview of these regulations.

9. Comment: Five commenters were of the opinion that HCFA should conduct a study to determine whether the added costs of CLIA to laboratories will justify the promulgation of the regulations.

Response: We disagree with the commenters' suggestions that further studies should be conducted to determine whether the added costs of CLIA are justified. Many provisions of section 1846 of the Social Security Act and section 353 of the Public Health Service Act can only be implemented after regulations are promulgated.

Unless the laws are repealed, we have no choice but to issue regulations. Congress has not given the Secretary the authority or the responsibility to conduct a study to determine if the laws should remain in effect. However, the Centers for Disease Control will be conducting CLIA-mandated studies in 5 other areas, such as quality assurance and personnel standards.

10. *Comment:* Three commenters were of the opinion that the only way rural health clinics (RHCs) could comply with the CLIA provisions would be if the requirements were modified for RHCs. Otherwise, RHCs should be exempted from CLIA.

Response: The law provides no authority for us to exempt laboratories in RHCs from CLIA requirements.

11. *Comment:* Two commenters were concerned that sanctions would put small laboratories out of business. The first suggested that HCFA impose a single sanction for all condition level deficiencies that are interrelated rather than a separate sanction for each condition level deficiency. This commenter feels that multiple actions could force a laboratory to close without having the opportunity to come into compliance. The second commenter feels that sanctions should be eliminated.

Response: Under the law, HCFA is required to impose those sanctions that are most likely to bring laboratories into compliance in the shortest possible time. However, HCFA will not necessarily be imposing separate sanctions for separate deficiencies, unless the nature of the deficiencies is so different that a different enforcement remedy is warranted for each. Also, when civil money penalties are imposed, a fine can be imposed for each violation. This is specified at section 353(h) of the PHSA.

12. *Comment:* Some commenters were of the opinion that dental laboratories and laboratories in Women's, Infants and Children's Clinics should be exempted from CLIA requirements.

Response: Any laboratory that fits the definition set forth at section 353(a) of the Public Health Service Act is subject to CLIA requirements.

13. *Comment:* Four commenters were of the opinion that suspending Medicare payments might result in discrimination against Medicare beneficiaries by denying them access to specific laboratory services.

Response: There is nothing to preclude HCFA from using Medicare sanctions in conjunction with CLIA sanctions in any situation of noncompliance. In fact, in the case of immediate jeopardy deficiencies, alternative sanctions will be paired with a principal sanction. For example, with immediate jeopardy deficiencies, HCFA would suspend the CLIA certificate immediately, and simultaneously suspend all Medicare payments. This insures protection of all patients using the services of the laboratory not just Medicare patients.

14. *Comment:* 15 commenters expressed concern regarding the potential costs of onsite monitoring. Several felt they might be able to defray costs if they had some input into scheduling and prior notice of on-site monitoring in order to avoid creating costly scheduling situations in their laboratories. Others disagreed with the method of determining costs for on-site monitoring and felt a specific fee schedule based on an average figure instead of number of hours would be less costly to them. One commenter suggested that laboratories holding certificates of waiver should be exempt from paying for on-site monitoring because of limited resources, low-volume of tests performed, and minimal risk to the public. Others want detailed information regarding costs, including hourly rates, frequency, duration and timing of monitoring. Several felt that because HCFA was requiring the monitoring, HCFA should pay for it.

Response: There will be at least 15 days notice before the effective date of the sanction of on-site monitoring in situations that do not pose immediate jeopardy and 5 days notice when there is immediate jeopardy. A fee schedule based on average fees rather than actual hours would benefit only those laboratories that require an above average number of hours of monitoring. The fairest approach will be to charge each laboratory for the actual number of hours used. Laboratories holding certificates of waiver will not be required to pay monitoring fees, because we do not intend to subject them to alternative sanctions as provided at § 493.1806(c) of this final rule. Our response to the request for detailed information about hourly rates, frequency, timing and duration of monitoring, is, as stated above, that we believe the fairest approach to be determination on a case-by-case basis.

15. *Comment:* Two commenters questioned the process by which HCFA decides to impose onsite monitoring.

Response: The decision to impose onsite monitoring is one which, as in the case of other sanctions, will be made on a case-by-case basis. It will take into account the specifics of each situation which will dictate the type of sanction most likely to motivate correction of deficiencies.

16. *Comment:* Two commenters were of the opinion that a suspension of Medicare payments would not encourage compliance or would not be a significant penalty for laboratories having a low volume of Medicare patients.

Response: We realize that not every available sanction will be appropriate for every laboratory. For this reason, in § 493.1804(d)(2) we specify that in selecting a particular sanction, HCFA's primary aim is to ensure that a laboratory corrects its deficiencies. It is up to HCFA to decide if the sanction would be sufficient in any given case to motivate the laboratory to correct deficiencies. Since neither the Medicare nor CLIA statute dictates that any particular remedy be used in any case of noncompliance, we believe that we have complete discretion to make enforcement choices.

17. *Comment:* One commenter expressed support for this regulation indicating that closing poor or marginal laboratories would be a desired effect of this legislation.

Response: We appreciate the commenter's overall support for this rule and are fully committed to the development of regulations that will implement CLIA effectively. However, the closing of poor or marginal laboratories is a goal of last resort. Our objective is first to take whatever enforcement action is likely to motivate the laboratory to correct the deficiencies.

18. *Comment:* Five commenters indicated their support for the imposition of alternative sanctions.

Response: We appreciate the support we have received for this rule and are committed to the development of regulations that reflect the enforcement-related aspects of the CLIA provisions.

19. *Comment:* Four commenters were of the opinion that punitive measures do not encourage compliance, and one stated that an educational approach would be more productive over the long run.

Response: Section 1846 of the Social Security Act and section 353 of the Public Health Service Act contemplate that adverse actions be taken against laboratories that have failed to quickly come into compliance. However, it should be noted that alternative sanctions do offer laboratories the opportunity to come into compliance within a specified period of time instead of immediately having their CLIA certificates suspended, limited, or revoked, or their Medicare approval cancelled. In addition, in cases of adverse action taken in response to

unsuccessful participation in proficiency testing, educational activities such as training and technical assistance may be used.

20. *Comment:* Eight commenters stated that HCFA cannot legally impose sanctions in the absence of published CLIA requirements.

Response: Another rule, identified as HSQ–176–FC and published elsewhere in this issue of the **Federal Register**, specifies the requirements for a CLIA certificate, and that rule is effective on the same day as these regulations. As noted in some of our other responses, the phase-in policy for effective dates of CLIA requirements will have a corresponding phase-in policy for enforcement procedures.

21. *Comment:* Six commenters disagreed with being sanctioned for noncompliance in proficiency testing.

Response: The law contemplates that we invoke sanctions for noncompliance in proficiency testing because successful performance of this testing is a requirement for obtaining a CLIA certificate. However, the law also provides that we may require additional training of personnel, technical assistance, or both in lieu of or in addition to sanctions or civil action for unsuccessful PT participation. In addition, during the phase-in of proficiency testing, as discussed in section D of program impact, some prior to the effective date of the applicable PT requirements.

22. *Comment:* Two commenters were concerned that available sanctions are subject to broad interpretation and may be applied inequitably.

Response: The regulations are rather specific as to appropriate sanctions in specific situations as a function of whether deficiencies are at the condition level, and if they are, whether the deficiencies pose an immediate jeopardy to the laboratory's patients or to the general public. HCFA has the discretionary authority to impose one or more principal or alternative sanctions, based on the severity and nature of deficiencies found during inspections of laboratories. If the deficiencies are determined to pose immediate jeopardy to the health and safety of individuals served by the laboratory or that of the general public, the sanctions imposed will, of necessity, be more severe than those used in situations which are less threatening, and will consist of at least one principal sanction. When there is not immediate jeopardy, alternative sanctions rather than principal sanctions would be imposed first, thus allowing the laboratory a longer period of time to come into compliance. If the laboratory fails to correct all condition level deficiencies within the specified timeframe, HCFA would impose principal sanctions.

The choice of alternative sanctions is based on the nature of the deficiencies. Therefore, regulatory guidelines that would cover every possible situation would be virtually impossible to develop. There would be no way to include in such guidelines every possible combination of deficiencies and therefore no way to develop policies on which alternative sanction(s) to impose in each case.

23. *Comment:* Thirteen commenters states that HCFA should develop a system for classifying the severity of deficiencies, and should delineate this system in these regulations. There were also requests from eight commenters for a formal link between deficiency type and sanction imposed, with many commenters expressing a lack of confidence in HCFA's "sole reliance" on the judgment of State surveyors when making a determination of compliance or noncompliance in a laboratory.

Response: In the future, HCFA may develop a system to classify the scope and severity of deficiencies with regard to CLIA requirements. However, one must remain cognizant of the fact that even if a scope and severity scale for deficiencies is developed, it would not lessen reliance on surveyor judgment in determining the existence of deficiencies or whether those deficiencies pose an immediate jeopardy. With regard to linking specific sanctions with certain deficiency types, we oppose the development of a formal link between each type of deficiency and the sanction imposed. Such a system would predetermine which sanction we must impose if a certain deficiency exists, and would be so rigid as to serve neither HCFA's nor a laboratory's best interests. Our position on the imposition of alternative sanctions is that we must maintain flexibility. We rely on the surveyor to assess the severity of each deficiency and to recommend to us whether each deficiency poses immediate jeopardy, to recommend whether an alternative sanction would be appropriate, and, if so, which one. Based on those recommendations, we will impose the alternative sanction that, in our judgment, would best encourage the laboratory to quickly correct its deficiencies.

The surveyors whom we employ to inspect laboratories are laboratory professionals. They are trained extensively by both HCFA and their respective States in proper inspection techniques under CLIA. They use their professional judgment and expertise in making recommendations. We expect that each surveyor will demonstrate sound judgment and make good decisions. However, there are "checks and balance" inherent in this system. The surveyors' recommendations are reviewed by the supervisory staff of the State agency or other HCFA agents, and are further reviewed by the HCFA regional office (RO). The RO makes the final determination of compliance or noncompliance and imposes the sanction(s) that would, in the opinion of the RO, most likely precipitate correction.

We reiterate, however, that State surveyors or other agents designated by HCFA to inspect laboratories are highly trained professionals. We do not believe that the differences in each surveyor's professional judgment would negatively affect a laboratory to the degree predicted by commenters, because one of the major objectives in the training of State health department personnel, State surveyors, and other HCFA agents is consistency in the application of all sanctions.

24. *Comment:* A large group of commenters expressed concern about the timeframe for responding to HCFA's written notice of sanction. They stated that the 15-day period of time between the notice of sanction and the actual imposition of the sanction is too short for a laboratory to obtain sufficient documentation in order to prepare a response. For this reason, they requested that the 15-day period be expanded to 30 days.

A few commenters stated that 5 days are insufficient to respond to the notice of, and/or correct, an immediate jeopardy situation.

A number of other commenters felt that HCFA should issue a statement to the laboratory, within a specified number of days after the receipt of the laboratory's response to the HCFA notice of sanction, in order to formally acknowledge the laboratory's response. One commenter stated that HCFA should include in its response a more "uniform" interpretation of the regulations to explain to the laboratory (i.e., a response in greater detail than what the State agency could provide) why the laboratory is out of compliance. A few other commenters requested that the notice contain additional sanction-specific information.

Response: We will not increase the 5-day and 15-day periods between notice of sanction and the actual imposition of sanction (or, in the case of civil money penalties, the effective date of accrual), because, regardless of whether there is immediate jeopardy or no immediate jeopardy, further delay in the imposition

of sanctions would mean further risk to the health and safety of the patients the laboratory serves and, in some instances, risk to the health of the general public. Moreover, the laboratory is actually aware of the deficiencies that need to be corrected for more than 5 or 15 days. Specifically, the laboratory is notified of deficiencies at the exit conference and written notification of deficiencies is provided within 10 days of the inspection.

Some commenters were concerned that we should send a formal acknowledgement upon receipt of a laboratory's response to the HCFA notice of sanction. We will acknowledge receipt of the laboratory's evidence of compliance or a credible allegation of compliance in the written decision at the end of the correction period. We have made it clear at § 493.1810(c) that at the end of this period, we will either confirm the imposition of sanction on the proposed effective date, or discontinue the imposition of the sanction. In either case, we believe it is unnecessary for HCFA to provide a "more uniform" interpretation of the regulations, since the States have been trained in our interpretation and use it in carrying out their survey and certification duties on behalf of the Secretary.

25. *Comment:* A few commenters requested that we not "duplicate" existing inspection and enforcement mechanisms currently used in provider (such as nursing facilities) which perform laboratory testing.

Response: We acknowledge the commenters' concern that these regulations might cause a possible "overlap" of inspection and enforcement activities in providers such as nursing facilities, which are surveyed under the authority of the Nursing Home Reform provisions of OBRA '87. However, the inspection and enforcement mechanisms under CLIA will remain separate from those used for other areas of patient care in such facilities. Section 353(b) of the Public Health Service Act (as amended by CLIA 88) does require that every laboratory soliciting or accepting materials for examination or diagnostic procedures have a certificate issued by the Secretary which permits the laboratory to perform that type of testing. This CLIA certificate indicates that the laboratory has met the requirements imposed under CLIA. These CLIA requirements apply to every laboratory that does testing that meets the CLIA definition, whether the laboratory is a freestanding facility or a component of a provider or other supplier. In fact, the nursing home requirements at 42 CFR 483.75(j)(l)(i) specify that if the facility provides its own laboratory services, the services must meet the applicable laboratory requirements in part 493 of the regulations. Therefore, the nursing home survey process requires that inspection of the facility against the laboratory conditions at part 493 to determine if the nursing home meets the requirements at § 483.75(j).

The new CLIA conditions will supersede the pre-existing conditions for coverage for independent laboratories as well as the laboratory requirements previously contained in the conditions of participation or conditions for coverage for laboratory services in other suppliers and in providers such as nursing facilities. The implementation of these requirements has been promulgated under a separate rule, published elsewhere in this edition of the Federal Register and identified as HSQ–176–FC.

26. *Comment:* A large number of commenters requested that HCFA consider factors such as the size and test volume of a laboratory when determining which sanctions to impose, particularly when the sanctions being considered involve a monetary penalty.

Response: These regulations set forth laboratory sanctions that directly or indirectly involve the expenditure of money by, or the loss of payment to, the laboratory. We are aware that such sanctions might be more easily borne by a large laboratory than a small laboratory. We also know that a sanctioned laboratory in a provider or supplier such as a hospital or physician's office might have access to greater financial resources and thus remain operational for a longer period of time than a similarly-sized free-standing laboratory (provided that HCFA does not suspend, limit, or revoke its CLIA certificate). We realize too that any laboratory which performs a low volume of tests has fewer specialties and subspecialties of testing to offset sanctioned categories.

As stated previously, our approach to imposing sanctions is one of flexibility, and our choice of the sanction(s) which we impose is guided not only by the severity of the deficiencies, but by the nature of the deficiencies and the corrections that must be made. HCFA decides which sanctions to impose on the basis of the surveying agency's recommendations. The size and test volume of a laboratory are among the factors considered in the process of reaching a decision. For example, if we impose a sanction against a small laboratory, we would try not to impose a sanction for which the monetary component would be large enough to force that laboratory to close rather than correct its deficiencies. In fact, with civil money penalties, the process involves the flexibility for HCFA to set the monetary amounts at lower levels for less severe deficiencies. However, for other sanctions in which expenditures of money are involved, such as a directed plan of correction, a deficiency that is relatively less serious in terms of negative patient outcomes is a deficiency, nonetheless, and may require a significant amount of money to correct, regardless of the size of the laboratory. The choice of sanction(s) could, therefore, precipitate closure of the facility if the laboratory's financial resources were depleted during the correction period.

27. *Comment:* Several commenters requested that HCFA implement a gradual phase-in of sanctions in order to afford laboratories (especially those that were not previously regulated under CLIA) additional time to educate their staff on the CLIA 88 conditions prior to being subject to sanctioning.

Response: Both this regulation and HSQ–176–FC (the rule delineating the conditions that laboratories must meet to operate under CLIA), published today, are effective six months from today. This delay in effective dates will afford the laboratory community ample time to become familiar with these requirements prior to the commencement of inspections under CLIA. Additionally, prior to the inspection of any laboratory under these requirements, laboratories that have followed appropriate application procedures, including the payment of required fees, will have been issued an initial registration certification that permits the laboratory to operate. The certificate to be issued after the inspection can be withheld and the registration certificate revoked for noncompliance with conditions of participation. The timing of the first inspection, however, is dependent on workload and other administrative factors and may not occur until quite some time following the issuance of the registration certificate. The period of time that a laboratory is permitted to operate under its registration certificate represents additional time that a laboratory will have to become familiar with the CLIA requirements and ensure that it is operating in compliance with those requirements prior to any inspection.

We have described two separate systems which we developed for the phase-in (delay in the imposition of) alternative sanctions. Both are

described under the Program Impact section (sections II D and E, respectively) of this preamble. The first specifies that for any laboratory with unsuccessful participation in proficiency testing, alternative sanctions will not be imposed at the time of the first citing of such unsuccessful participation in proficiency testing. At section II E, we have described a separate system for the phase-in of alternative sanctions against laboratories not previously regulated under CLIA or Medicare which have condition level deficiencies in areas other than PT. Our rationale for this policy is delineated below.

The requirements established under CLIA and published today will likely result in some changes in the operations of approved PT organizations and their testing procedures. We do not believe it would be equitable to hold previously regulated laboratories, that have routinely participated in PT programs, immediately accountable for changes made in the PT process. We do not believe that these laboratories should be penalized while proficiency testing providers are fine tuning their program to eliminate any operational problems that may exist since changes were implemented as a result of CLIA '88. With respect to previously unregulated laboratories, we estimate that as many as one half of these laboratories have never participated in PT testing programs. These laboratories will also need a phase-in period to become familiar with both the technical and operational aspects of initiating relationships with PT organizations and participating in their programs. With regard to laboratories which were not previously regulated under CLIA or Medicare, we believe that a phased-in system of enforcement for conditions other than PT is an equitable alternative to the immediate sanctioning of such laboratories when their noncompliance with CLIA condition level requirements does not constitute immediate jeopardy. Since many of the newly regulated laboratories have never before been subject to any onsite Federal inspections, we believe that our emphasis on working with laboratories to advise them in correcting deficiencies during the first inspection will be more effective in achieving our goal of laboratory quality then using punitive sanctions. These laboratories which have never been regulated at the Federal level require additional time to become familiar with CLIA and to understand the inspection process and the requirements of the regulations.

28. *Comment:* Two commenters stated that a single sanction should be imposed for all condition level deficiencies.

Response: We disagree. Both section 1846(b)(3) of the Social Security Act and section 353(h)(3) of the PHS Act give the Secretary the authority to develop procedures with respect to when and how the alternative sanctions are to be used. Therefore, whether single or multiple sanctions are imposed will depend upon the specific situation within a laboratory as determined by HCFA.

29. *Comment:* Two commenters thought that the activities of the State monitor should be more clearly delineated in the regulation.

Response: We accept this comment and have added clarifying language at § 493.1836(a)(1), which explains that the State monitor does not have managerial authority over the laboratory's personnel, and that its sole responsibility is to oversee whether corrections are made.

30. *Comment:* Ten commenters were of the opinion that suspension of Medicare payment is too harsh a remedy, may not be appropriate for situations that do not pose immediate jeopardy and should not be implemented until laboratories receive additional opportunities to correct the deficiencies.

Response: With regard to the perceived harshness of the sanction, we can state that all of the alternative sanctions are intended to constitute a means by which laboratories with deficiencies that do not pose immediate jeopardy can avoid immediate cancellation of Medicare approval or revocation of any type of CLIA certificate. The sanction is intended to be harsh enough to motivate correction, but less harsh than Medicare cancellation or CLIA certificate revocation.

31. *Comment:* Five commenters expressed the opinion that the regulations should contain assurances that a suspension of Medicare payments for laboratory services by a provider could not result in the suspension of payments for any non-laboratory services as well. Another two commenters expressed concern that in terms of hospital-based laboratories, it is unclear how payment can be suspended for specific services when diagnostic related group (DRG) payment is an all-inclusive fee.

Response: In the case of providers that are not subject to the prospective payment system (PPS), we will use an identifier code to distinguish laboratory services from other services and thus ensure continuation of Medicare payment for those other services. However, we could not suspend Medicare payments in exact amounts under the PPS system. We can, by approximation, suspend Medicare payment for laboratory services rendered to inpatients of hospitals operating under PPS. We can do this by reducing the total Medicare payment to the hospital by an amount equal to the most current average percent of diagnostic related group (DRG) payments that reflects the laboratory component of each DRG.

32. *Comment:* Five commenters offered the opinion that laboratories may have totally valid reasons for withholding information from HCFA and because of these reasons should not be penalized as specified at § 493.1840.

Response: The statute authorizes the Secretary to suspend, revoke, or limit a laboratory's certificate if the laboratory has failed to comply with reasonable requests of the Secretary for any information that the Secretary concludes is necessary to determine the laboratory's continued compliance with requirements and continued eligibility for a CLIA certificate. The statute explicitly authorizes the limitation or suspension of the certificate prior to hearing, as provided in § 493.1844(e)(2)(ii)(B) of this final rule, when a laboratory fails to provide information that we believe is necessary to enable us to undertake our statutory responsibilities. The laboratory could attempt to justify the withholding of information at the time of that hearing.

33. *Comment:* Four commenters voiced the opinion that if a laboratory's CLIA certificate has been revoked within the preceding two-year period, HCFA should initiate adverse action, not only against its owner or operator, but also against those directors involved in the operation of the laboratory.

Response: We have added a definition of "operator" which clarifies that directors of laboratories who are involved in their overall operation, are knowledgeable about the workings of the entire facility, and who bear primary responsibility for the safety and reliability of laboratory testing, are considered operators for the purpose of this regulation. It is our belief, consistent with the direction given by Congress in section 353(i)(3) of the PHS Act, that any laboratory director who meets the criteria as an operator should not be permitted to operate or own any laboratory within 2 years of operating a laboratory which has had its CLIA certificate revoked, as set forth at § 493.1840(a)(8) of these regulations.

34. *Comment:* Four commenters questioned that rationale of HCFA notifying the Office of the Inspector General (OIG) whenever HCFA initiates an adverse action to suspend, limit, or revoke a laboratory's CLIA certificate based on noncompliance with CLIA requirements by an owner or operator of a laboratory.

Response: We plan to inform the OIG of any adverse actions we impose against laboratories if we determine there has been a violation of any of the laws enforced by the OIG. For example, the violations listed at § 493.1840(a)(1), (a)(2), (a)(6), or (b) involve misrepresentation, fraud against the Medicare and Medicaid programs, or some other type of intentional violation of requirements for the Medicare, Medicaid, or CLIA program that may warrant action by the OIG.

35. *Comment:* Some commenters were opposed to the provision at § 493.1840(a)(8), specifying the use of principal sanctions against owners and operators of groups of legally related laboratories merely because one or some of these laboratories were out of compliance. This commenter stated that mere ownership of a laboratory which has been sanctioned in the past should not jeopardize the operations of some other distantly related laboratory and further requested that we clarify the definition of "owned and operated". Another commenter suggested that laboratories which were sanctioned by having their certificate revoked within the last two years should be allowed to have the sanction removed after only one year.

Response: It is the law itself which establishes the prohibition. It provides specifically that the owner or operator of a laboratory that has had its certificate revoked may not own or operate a laboratory for two years after the revocation of the CLIA certificate of the initially sanctioned laboratory. HCFA has no choice but to implement this provision, found at section 353(i)(3) of the Public Health Service Act. We therefore did not accept this comment. The final rule also defines the terms "owner" and "operator", and specifies the types of ownership relationships and operator positions that would prohibit ownership or operation of a laboratory for two years.

36. *Comment:* A few commenters had questions regarding the application of principal sanctions. One questioned whether there is a conflict between § 493.1816(b) and § 493.1820 because of the lack of specified timeframes for implementing and keeping alternative sanctions in effect. The same commenter also wants to know when § 493.1820 is used exclusively. Another commenter wants us to clarify that the cancellation and suspension sanctions referred to in the existing regulations are the same as those in the proposed rule which guarantee each laboratory the right to due process.

Response: The distinction between § 493.1816(b) and 493.1820 is that the latter deals with all deficiencies and the former applies to deficiencies not at the condition level. The maximum timeframes for the duration of alternative sanctions is specified as 12 months at § 493.1820(c) and the timeframe for implementation is specified at § 493.1810. The laboratories' right to due process is specified at § 493.1844.

37. *Comment:* Three commenters were of the opinion that suspension of payment or cancellation of Medicaid approval should be limited to condition-level noncompliance.

Response: The suggestion made by these commenters reflects what the policy is. Both alternative sanctions and principal sanctions are imposed only for condition-level deficiencies.

38. *Comment:* Two commenters requested that we add to the menu of available sanctions some less severe penalties such as probation, reprimand and supervision.

Response: The phased-in enforcement plan described in the response to comment 27, should serve the same purpose as the type of sanctions suggested by the commenters.

39. *Comment:* One commenter stated that if payments were suspended due to a specific condition-level deficiency, the rule would prohibit payment if that deficiency were corrected but other unrelated condition level deficiencies still exist. The commenter wants the language changed so that suspension of payment will end once the laboratory corrects the sanctioned deficiency even if unsanctioned deficiencies still exist. Another commenter cited § 493.1807(b)(2) which states that it appears that HCFA may impose one or more of several sanctions when condition-level deficiencies are found without necessarily using a suspension of payment sanction.

Response: With the exception of the suspension of Medicare payment for specific specialties or subspecialties, alternative sanctions are not deficiency-specific. Therefore, if a laboratory were to correct the noncompliance in the specialties or subspecialties for which a suspension of Medicare payment has been imposed, the suspension of payment would be lifted upon verification of correction of those specific deficiencies. However, if any condition-level noncompliance remains uncorrected, we will continue to impose some form of alternative sanctions, and will lift only those sanctions which we deem appropriate as we verify correction of each of a laboratory's condition-level deficiencies. For example, if a suspension of payment for all specialties and subspecialties had been imposed, it would continue in effect until all deficiencies are corrected.

40. *Comment:* One commenter questioned whether the corrective action specified in a directed plan of correction are administrative or technical in nature.

Response: It is difficult for us to know exactly what this commenter means by the terms "administrative" and "technical". However, these definitions are immaterial in the sense that under a directed plan of correction, every deficiency must be corrected, whatever its form

41. *Comment:* One commenter suggested that a directed plan of correction should be the preferred sanction used when the deficiency does not pose immediate jeopardy.

Response: As stated above, the decision as to which sanction to impose will be made on a case-by-case basis. It will be based on the specifics of each situation which, in HCFA's judgement, will dictate the type of sanction most likely to motivate correction of deficiencies.

42. *Comment:* One commenter stated that any rule linking Medicare status with CLIA must be promulgated pursuant to notice and comment procedures under the Medicare law rather than under CLIA.

Response: Section 6141 of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239) requires all laboratories that participate in Medicare to meet the CLIA 88 requirements. Therefore, we believe we are justified in consolidating regulatory provisions implementing the Medicare laboratory provisions of the Social Security Act and the CLIA provisions of the PHS Act.

43. *Comment:* One commenter asked if the wording in the rules might be made clearer regarding the criteria for selecting a particular sanction.

Response: We believe it is inadvisable to have a rigid system of specific sanctions for each deficiency. HCFA has flexible enforcement capabilities in order to treat each noncompliance situation on a case-by-case basis.

44. *Comment:* One commenter stated that failing to charge Medicare beneficiaries for services for which Medicare payment has been suspended is an inappropriate sanction and would

accomplish nothing because laboratories would then attempt to be reimbursed by beneficiaries' supplementary insurance plans, if applicable.

Response: We consider charging the Medicare beneficiary's private insurance carrier tantamount to charging the beneficiary, because that action would, in essence, be predicated on the assumption that the beneficiary is responsible for payment, although indirectly. We have clarified in the regulations at § 493.1826 and § 493.1828 that the laboratory must agree not to charge the beneficiary's private insurance carrier, in order to avoid immediate cancellation of Medicare approval.

C. Civil Money Penalties (Section 493.1834)

1. *Comment:* Many commenters believed that the civil monetary penalty range of $3,050–$10,000 for immediate jeopardy situations is too high.

Response: In immediate jeopardy situations, HCFA may impose from $3,050–$10,000 for each day of noncompliance, or for each violation. $10,000 is the maximum amount specified by section 1846 of the Act and section 353(h) of the PHS Act. $3,050 is the lowest amount judged by HCFA, based on a review of a variety of state civil money penalty systems available under various State licensure laws, to be effective in encouraging compliance in an immediate jeopardy situation. HCFA will assess each laboratory's noncompliance on an individual basis in order to determine the amount of the penalty. We believe that we are establishing a very flexible system by designating the highest ⅔ of the civil money penalty range for immediate jeopardy situations only. Since deficiencies that pose immediate jeopardy occur much less frequently than those that do not, relatively few laboratories will be subject to the higher fines. Moreover, the range of civil money penalties available for immediate jeopardy deficiencies is so broad that a laboratory with such deficiencies may not be fined at the maximum level. If some laboratories are fined at the maximum level, the amounts of the fines are justified by fact that their deficiencies could cause life-threatening situations.

HCFA's long-standing policy is to afford providers and suppliers an opportunity to correct deficiencies before taking adverse action. Before a civil money penalty is imposed, HCFA will give the laboratory written notice of its intent to impose the penalty. The penalty does not begin accruing until the laboratory is officially informed of its deficiencies and the 5-day or 15-day notice period ends. Moreover, the civil money penalty is not collectible until after the 60-day period for requesting a hearing (if the laboratory does not request a hearing) or, if the laboratory requests a hearing within the prescribed timeframe, until after the hearing decision that upholds the imposition of the penalty.

2. *Comment:* Many commenters were concerned that civil money penalties could financially decimate a laboratory.

Response: We recognize that some laboratories may experience more hardships and financial burdens associated with civil money penalties than others. However, HCFA is charged with carrying out the law by promulgating regulations that reflect what we believe to be the most effective means of implementing the statute. If deficiencies in a laboratory remain uncorrected for so long, for example, that the civil money penalties decimate that laboratory, we can only conclude that the protection of the safety of the patients had to supersede continued operation with such serious deficiencies.

3. *Comment:* Several commenters had questions regarding the factors HCFA considers in determining the civil money penalty amount. Many suggested that volume of laboratory tests should be considered in determining the amount of the civil money penalty.

Response: As specified at § 493.1834(d), in determining the amount of the penalty, HCFA takes into account the following factors:

a. The nature, scope, severity, and duration of the noncompliance.

b. Whether the same condition level deficiencies have been identified during three consecutive inspections.

c. The laboratory's overall compliance history including, but not limited to, any period of noncompliance that occurred between certifications of compliance.

d. The laboratory's intent or reason for noncompliance.

e. The accuracy and extent of laboratory records and their availability to HCFA, the State survey agency, or other HCFA agent.

We do not believe that we should take into consideration the volume of laboratory tests performed. The correlation between deficiencies and amounts of civil money penalties should be based on severity of noncompliance and the speed with which corrections need to be made, not the laboratory's workload. A relatively small laboratory may exhibit extremely serious deficiencies that require immediate correction for the sake of the patients serviced. We believe that a relatively high civil money penalty would be the best incentive for prompt correction.

4. *Comment:* Several commenters were concerned about the accrual of a civil money penalty until the laboratory's condition level compliance is verified and believe this provision places the laboratory at the mercy of the surveyor's schedule. The following is a summary of their comments and recommendations.

- Require verification of compliance within a specified time period such as 30 days, or within 2 days of the laboratory's request for reinspection.
- Provide that the accrual of the penalty amount ends on the date that the laboratory achieves compliance, or on the date it requests reinspection.
- Accept as establishing compliance a laboratory's good faith representation, or the submission of suitable documentation, or establish it through an inspection visit.

Response: We believe that timeframes for revisits by the survey agency constitute a subject for operating guidelines and should not be included in regulations. We also believe it is the survey agency's responsibility to verify a laboratory's compliance in a timely manner. However, the timeframes for resurveys could vary from State to State and within a State because of various factors, such as variations in geography and available personnel. Therefore, we have concluded that if the laboratory can produce credible evidence at the time of the resurvey, that compliance was achieved before the resurvey, the civil money penalty will stop accruing as of the date that the compliance was achieved. We have revised § 493.1834(f)(2) to so provide.

5. *Comment:* Several commenters were concerned about the start dates and due dates of civil money penalties and about HCFA's computation of the civil money penalty before a fair hearing. With regard to the latter point, one commenter stated that such a policy contradicts the statutory requirement that civil money penalties not be assessed before a hearing.

Response: The civil money penalty begins to accrue 5 days after notice of intent to impose the penalty (in immediate jeopardy situations) and 15 days after notice when there is no immediate jeopardy, because we believe that prompt sanctioning is necessary to ensure prompt correction of deficiencies. However, as specified in § 493.1834(g), HCFA does not actually impose the civil money penalty until the later of the following:

• The end of the 60-day period for requesting a hearing, if the laboratory does not request a hearing, or

• If the laboratory does request a hearing within the prescribed timeframe, after a hearing decision that upholds imposition of the penalty is issued.

6. *Comment:* Several commenters objected to the 35% reduction in civil money penalties if no hearing is requested.

Response: We did not accept this comment. The 35% reduction of the civil money penalty if a laboratory does not request a hearing was proposed to reflect a savings of costs that would otherwise be incurred by the Federal government if a hearing were conducted. It is at the sole discretion of the laboratory not to request a hearing and accept the 35% reduction. Such a policy does not restrict the laboratory's legal right to due process because the decision to waive the right to a hearing is strictly voluntary.

7. *Comment:* Two commenters are concerned about the provision that would permit HCFA to increase the civil money penalty if a laboratory, which alleges compliance, is found after a revisit to still be out of compliance. They believe HCFA should increase the civil money penalty only if the laboratory willfully or intentionally misrepresents that it has achieved compliance.

Response: The task of determining whether a laboratory intentionally or willfully misrepresented compliance would be a responsibility too burdensome for HCFA to undertake. The regulation provides that the amount of any civil money penalty, including any proposed increase or decrease to the initial amount, will be based on any change in the seriousness of the deficiencies.

8. *Comment:* One commenter believes the laboratory should be entitled to a hearing with respect to any increase in the civil money penalty amount.

Response: As we explained in a previous response, if a hearing is requested by the laboratory, the notice of the total penalty amount is not sent until the administrative law judge issues a decision adverse to the laboratory following the hearing. The administrative law judge will base his or her calculation of total penalty amount on the per day or per violation rate times the number of days of noncompliance or number of violations. The hearing will, therefore, be held after the revisit, if a revisit was conducted. Any increase in the per day or per violation rate will be proposed by HCFA between the revisit and the hearing. We have clarified this policy at § 493.1834(d)(4). However, as specified at § 493.1844(d)(4), the amount of a civil money penalty to impose per day or per violation is not an initial determination and therefore is not subject to appeal; rather, the imposition of an alternative sanction, (in this case a civil money penalty) is the action that is subject to appeal.

9. *Comment:* Three commenters expressed overall concern about the implementation of civil money penalties. One commenter recommended a cap be placed on the amount of daily fines assessed while an appeal is pending, to ensure that the total penalty is not disproportionately large. The second commenter believed the regulations should contain standards to be applied by HCFA in determining whether to impose a civil money penalty to assure fair and even imposition of a civil money penalty and such standards would be helpful in avoiding allegations of arbitrary and capricious actions. The third commenter suggested the regulation should be revised to make it clear that civil money penalties will be used only when a laboratory fails to take corrective action to eliminate condition-level deficiencies within a reasonable amount of time and urged HCFA to use civil money penalties sparingly.

Response: We appreciate the concerns of the commenters. There is already a statutory cap of $10,000 per day or per violation. However, the sooner the laboratory corrects its condition-level noncompliance, the sooner such civil money penalties will cease accruing while the hearing is pending. Thus, to a significant degree, the laboratory can control whatever liability it might have for a civil money penalty. In response to the suggestion that the regulation contain standards to determine whether or not to impose a civil money penalty, this decision is made on a case-by-case basis. HCFA will select the sanction(s) that are most likely to encourage the laboratory to meet CLIA requirements promptly. In response to the suggestion that civil money penalties be used only when a laboratory fails to take timely corrective action to eliminate condition-level deficiencies, such is the case with all alternative actions as specified at § 493.1810.

10. *Comment:* One commenter recommended that § 493.1834(1) provide for a specific rate of interest, such as 1 percent above the U.S. Treasury Bill rate.

Response: We have revised § 493.1834(i) to specify that the interest rate applicable to civil money penalties is the rate set forth in § 405.376(d) of the HCFA regulations, which states that the interest rate on such payments will be the prevailing rate(s) specified in bulletins issued under § 8020.20 of the Treasury Fiscal Requirements Manual.

D. Refund of Medicare Payments (Section 493.1830)

We proposed to establish an alternative sanction that would require a laboratory with deficiencies, in lieu of having its Medicare approval canceled, to promise to refund Medicare payments made during the time allowed for correction of deficiencies if the deficiencies were not corrected during that time period, and to not charge the beneficiary for any services for which the laboratory refunded the Medicare payment.

Comment: We received 17 comments regarding this provision. Eleven commenters felt that the sanction would be unduly harsh, since the laboratories would have performed the tests "in good faith." Five commenters suggested that payments only be refunded for areas of noncompliance, while five also questioned the necessity of including this sanction in this regulation at all, since the threat of suspension, limitation, or revocation of the CLIA certificate would presumably be sufficient incentive to a laboratory to correct its deficiencies. Four commenters were of the opinion that if a laboratory refunded Medicare payments to HCFA, HCFA should refund the money to that laboratory once compliance is achieved. Two commenters stated that there should be a limit to the total amount of Medicare payment that must be refunded. Other comments included concerns that this sanction would serve to effectively penalize laboratories that participate in Medicare. Some commenters stated simply that it would be undesirable from a fiduciary standpoint to not privately charge Medicare beneficiaries for tests if they are indeed performed.

Response: After further consideration of this proposed sanction, we decided to withdraw it. We considered, for instance, that access to laboratory testing might be reduced if many laboratories chose cancellation of their Medicare approval rather than refund Medicare payments. Accordingly, we have removed this sanction from the final rule.

E. Notification of Clients of Sanctioned Laboratories (Section 493.1832)

1. *Comment:* Many commenters were generally opposed to client notification. Eleven commenters felt that laboratory clients should only be notified of a

laboratory's sanctioning in cases of immediate jeopardy.

Response: The notification of clients of sanctioned laboratories may be necessary to provide these clients with the information required to make an informed decision regarding the retesting of specimens. HCFA will decide whether laboratory clients should be notified of any condition-level noncompliance in a laboratory, not only that which poses immediate jeopardy. Physicians, other providers and suppliers, and other clients who depend on a laboratory for accurate testing of specimens should be informed at HCFA's discretion when a specialty or subspecialty of tesing at that laboratory is not being properly performed. Informing laboratory clients of condition-level noncompliance would facilitate an informed decision regarding the need for retesting of patients. Further, section 353(n) of the PHS Act requires the Secretary to issue an annual report that identifies all laboratories that have been given a principal or intermediate sanction, convicted of a criminal violation, subject to a court injunction, or excluded from participation in Medicare or Medicaid.

2. *Comment:* A few commenters stated that laboratory clients should be notified only if a laboratory has had its CLIA certificate suspended and its Medicare approval cancelled.

Response: Waiting until a principal sanction is imposed could create an unnecessary risk. If the noncompliance identified in a laboratory does not pose immediate jeopardy to health and safety, Medicare approval may continue for up to 90 days, and its CLIA certificate may not be revoked until after a hearing (even though the laboratory may have alternative sanctions imposed during that time). If we were, in all cases of noncompliance, to notify laboratory clients only after these principal sanctions have been imposed, we would be waiting until all other attempts at corrective action had failed. Clients, therefore, would not have the opportunity to make timely informed decisions about retesting or the need to send specimens to other laboratories during a period of time in which the danger to the patients remained unchanged or even worsened.

3. *Comment:* Many commenters felt that the notification of a sanctioned laboratory's clients would be too burdensome for the laboratory, physicians and other clients, and the States.

Response: We recognize that the process of notification of a laboratory's clients means more work for the laboratory, which would have to provide the list of clients, if requested; the State, which will have the responsibility of notifying these clients, and clients who may find it necessary to notify patients about being retested. However, the risk to patients is significant if clients are not notified in cases where HCFA makes the decision that such notification should take place. Moreover, although we recognize an increased workload, we do question the extent of the work burden on laboratories since the names and addresses of their patients and other clients would already be compiled for billing purposes.

4. *Comment:* A few commenters voiced concern over the difficulty of notifying past patients of laboratory clients.

Response: We would expect that most providers and suppliers keep, for their own information and protection, historical records of patients for a specified number of years. However, we have not issued regulations regarding the notification of individuals who are patients of the laboratory's direct clients, and therefore indirect clients of the laboratory. We consider it beyond the purview of this regulation to regulate the actions of the physicians, providers and other suppliers who are users of a particular laboratory's services. Moreover, requirements for notifying such an extensive network of patients would be virtually impossible for HCFA to enforce. We, instead, leave such notification decisions to the health care facilities and professionals who referred their patients to a particular laboratory. In addition, as discussed previously under client notification issues, HCFA will publish a laboratory registry annually that will be accessible to the general public and will contain information that is useful in evaluating the performance of laboratories.

5. *Comment:* Several commenters were concerned that HCFA has no statutory authority to require the notification of clients of sanctioned laboratories.

Response: Section 1846(b)(1) of the Act requires the Secretary to develop "a range of intermediate sanctions" and section 1846(b)(3) of the Act and section 353(h)(3) of the PHS Act specify that the Secretary shall establish procedures with resect to when and how to carry out the imposition of those sanctions. We are using this discretionary statutory authority to notify clients of sanctioned laboratories as necessary to protect the health and safety of a laboratory's clients or the public health.

6. *Comment:* Five commenters expressed concern that the information contained in the client notification letter would be insufficient for a client to make an "informed decision" regarding how to notify and retest patients.

Response: A client will receive notice that a laboratory it uses for specimen testing has been sanctioned by HCFA. The client will be advised of the nature of the laboratory's noncompliance and, if the client requires additional information or clarification in order to make an informed decision regarding patient notification and retesting, or the use of another laboratory's services, it is the responsibility of that client to contact the State agency or the HCFA regional office to obtain this information or clarification.

7. *Comment:* Thirteen commenters were concerned that the notification of physician clients of sanctioned laboratories may increase physician's malpractice liability, and may irrevocably harm the reputations of both the laboratory and the physician.

Response: Physicians are responsible for the diagnostic procedures they order for their patients. It is therefore the responsibility of the physician to remain informed of diagnostic services that are substandard. Referring patient specimens, out of lack of information, to any diagnostic service (e.g., a laboratory) that does not comply with congressionally mandated Federal requirements for health and safety could create a much greater risk to a physician's malpractice liability and reputation than would the retesting or redirecting of patient specimens to another laboratory, based on the knowledge of noncompliance in the laboratory ordinarily used. Moreover, we cannot develop policies based on a concern for the reputation of the laboratories. If sanctioned laboratories correct their deficiencies, clients (if they were notified of the sanction) will be notified that the adverse actions have been rescinded. Any remaining negative impact on the reputation of a laboratory is the result of that facility's noncompliance, and not the result of HCFA's enforcement of health and safety requirements that are specified in the Federal law.

8. *Comment:* Several commenters were concerned that the 10 calendar days afforded to a sanctioned laboratory to submit its list of names of all of its clients to HCFA, the State, or other HCFA agent is too short.

Response: The 10 day timeframe is necessary to minimize the period between the identification of a laboratory's noncompliance and the notification of its clients of the sanctioning in order for the clients to make informed decisions regarding the

health of their patients and the need for retesting.

9. *Comment:* Seven commenters expressed concern that the notification of patients by clients would unduly alarm the patients.

Response: The notification of patients by their physicians, providers, or other suppliers that the retesting of their specimens is necessary due to laboratory noncompliance may initially be unsettling to some partients. However, the client can phrase this notice in such a manner as to minimize patient fear. In the cases of specimens which require retesting, the client can explain that the retesting is in the best interest of the patients' health and safety.

10. *Comment:* Several commenters suggested that it would be easier and more cost-effective for HCFA to place a notice of laboratory sanctioning in a local newspaper than to individually notify each client.

Response: HCFA routinely places notices in local newspapers of the termination of provider agreements and supplier participation in the Medicare program.

The problem with relying solely on this method of notification for laboratory clients is that not every client of a particular laboratory will necessarily read the appropriate paper on the particular day a notice is published. Since many laboratories routinely test specimens outside of their locale, a notice placed in a local paper might not be useful. To make certain that every laboratory client is aware that a laboratory is sanctioned, we must, in cases deemed appropriate by HCFA, notify each client individually in addition to publishing a notice in the local newspaper.

11. *Comment:* One commenter questioned whether the client notification would include specific information, such as areas of specific failure in proficiency testing.

Response: We will include in the client notification the nature of the noncompliance which led to the sanction. We have clarified this at § 493.1832(b).

12. *Comment:* One commenter stated that the notification of laboratory clients should be transmitted through the Department of Health and Human Services or the appropriate HCFA regional office instead of through the State agency, since the Department of HCFA letterhead "carries more weight" than that of the State, and State agencies would not have sufficient resources to handle such a task.

Response: State agencies are agents of both the Department and HCFA, and therefore can appropriately be given full regulatory authority to notify clients of sanctioned laboratories. As part of the implementation of the CLIA inspection and certification program, States will receive from HCFA sufficient resources to handle their additional responsibilities under CLIA.

F. Correction of Deficiencies (Sections 493.1810–493.1838)

1. *Comment:* Fifteen commenters voiced concern with the procedures for revisits. Of these fifteen, seven had questions regarding the duration of alternative sanctions, stating that §§ 493.1810 through 493.1816 are confusing, and that it is unclear whether sanctions are lifted on the date correction has been made, or on the date of a revisit which serves to verify correction. Four commenters requested that we develop a mechanism by which to ensure that revisits are conducted within a minimum specified amount of time after a credible allegation of compliance is given by the laboratory to the State, so that sanctions may be removed as soon as possible if the survey agency agrees that compliance has been achieved. One commenter suggested that we schedule the revisit in the notice of sanction. Another commenter, concerned that a request for a revisit may be denied, stated that a laboratory should be able to "self-certify" correction of its deficiencies. Two commenters felt that sanctions should not continue to be imposed if the laboratory makes a credible allegation of compliance, but the revisit has not yet been conducted. Two commenters requested that the term "credible allegation of compliance" be defined, and that the requirement that the allegation be submitted before a revisit can be scheduled be included in the regulation, as well as the preamble.

Response: Upon receiving a credible allegation of compliance from a laboratory, the State survey agency or other HCFA agent will determine whether compliance can be certified on the strength of the evidence presented by the laboratory in the verbal or written credible allegation. If this is the case, the appropriate sanctions will be lifted according to the procedures outlined at § 493.1810(e) of these regulations. However, it is frequently necessary for the survey agency to schedule a revisit to the laboratory in order to verify that compliance has been achieved. Revisits are always scheduled upon the receipt of a credible allegation of compliance and are scheduled to take place as soon as possible, but the length of time between the credible allegation and the visit can vary. For this reason, we will inform the laboratory that if, during the revisit, it can be determined that compliance was achieved prior to the revisit, the sanctions will be lifted as of that earlier date. (We have clarified this policy at § 493.1820(b).) We would, however, not categorize this process as a laboratory's "self-certification" of compliance, because certifications of compliance can only be made by HCFA or HCFA agents. Because it is impossible to predict the date on which a laboratory will be capable of making a credible allegation of compliance, we cannot accept the suggestion that the date of the revisit be contained in the notice of sanction. Moreover, such a policy of including a prospective revisit date in the notice of sanction would imply that the revisit is automatic although it is not. It must follow a credible allegation of compliance submitted by the laboratory. We have added a definition of "Credible allegation of compliance" in § 493.2, and clarified the above described policy in § 493.1810. Specifically, a "credible allegation of compliance" means a statement or documentation by a representative of a laboratory with a positive history of correction of noncompliance or a history of compliance. The allegation must be realistic in terms of the likelihood that the laboratory has been able to accomplish the corrective action within the specified timeframe, and indicate that the noncompliance has been resolved.

2. *Comment:* Several commenters had concerns regarding the formulation and use of the plan of correction, stating that guidelines for the formulation of a plan of correction should be published in these regulations as an aid to small laboratories, and that HCFA instead of the survey agency should be the one to monitor correction of deficiencies.

Response: The State agency or other HCFA agent which has inspected the laboratory has the necessary background knowledge to assist the laboratory in the formulation of the plan of correction, and to monitor the corrections, as specified on that plan of correction.

3. *Comment:* Many commenters had various questions regarding the timeframe for correction of deficiencies. Some of these commenters requested more time to correct deficiencies than that set forth in this proposed rule. Others requested additional time in which to fully pay a civil money penalty.

Response: In order to minimize the period of time in which a laboratory continues to operate with deficiencies, albeit under sanction, § 1846 of the Act

prohibits such laboratories from receiving Medicare payments for longer than one year from the date the noncompliance was initially identified. If one or more revisits confirm that a laboratory still has deficiencies one year from the date the noncompliance was initially identified, HCFA also notifies the laboratory no less than 15 days prior to taking such action, of its intent to suspend, limit, or revoke the laboratory's CLIA certificate, and of a laboratory's right to a hearing.

In response to the request for additional time to fully pay a civil money penalty, we have provided in the regulation at § 493.1834(h) for an extended payment schedule for laboratories that cannot pay the total amount of their civil money penalties by the due date. In no instance will the extended payment schedule exceed 12 months from the original due date. The details of this extended payment plan will be included in HCFA's operating guidelines.

4. *Comment:* One commenter questioned the absence of OMB approval of the plan of correction provision in these regulations under the Paperwork Reduction Act of 1980. Another commenter stated that our initial estimate of 5 hours needed to formulate a correction plan is unrealistic.

Response: The timeframe of 5 hours to complete a plan of correction is simply our initial estimate. When the Office of Management and Budget reviews the plan of correction requirements in order to refine the assessment of the time which would be needed to complete this document, and approves it along with other documents to implement the CLIA program, we will publish a notice in the Federal Register.

5. *Comment:* Two commenters think the contents of a plan or correction should be more explicitly explained, particularly when the plan concerns staffing requirements. For example, in a rural area, where recruitment of qualified people is difficult, is a plan of correction calling for simply an advertisement in the paper sufficient?

Response: This level of specificity is inappropriate for regulations. Moreover, broad policies relating to the appropriateness or inappropriateness of plan of correction items would be inconsistent with the approach of evaluating each laboratory's deficiency(ies) on a case-by-case basis.

G. Limitation of Certificates Based on the Test Level Rather Than the Specialty or Subspecialty Level

Comments: In response to our request for comments on the above noted alternative, we received numerous comments all in favor of applying the sanction at the test level.

Response: We appreciate the response to our request. As soon as we have the systems capability to impose limitations at the test level, we will initiate the policy and procedural changes necessary to do so. In the meantime, any laboratory found to be noncompliant in the testing of an individual analyte may, without sanction, voluntarily agree to cease testing of the analyte, according to the procedures at § 493.1832(b)(2). If the laboratory refuses to stop testing the analyte, HCFA may consider the continued testing an immediate jeopardy and impose a principal sanction as described at § 493.1812.

H. Appeal Rights (§ 493.1844)

1. *Comment:* Numerous commenters requested that the HCFA not impose any sanction until after a hearing.

Response: Consistent with both the Medicare and CLIA statutes, we believe that it is important to establish an enforcement process that minimizes the time between the identification of deficiencies and the taking of remedial action. The surest way we know to accomplish this objective is to provide prior notice of an impending sanction with the opportunity for a hearing after the sanction has been imposed. To provide hearings prior to the imposition of sanctions would enable deficient laboratory practices to remain in place for extended periods of time which we believe to be an unacceptable price for the public to pay.

Section 1846 of the Medicare statue specifically directs the Secretary to minimize the time between the identification of deficiencies and the imposition of sanctions, and CLIA clearly suggests the same course. Section 353(i), for example, is notably different from section 353(h). The former requires prior hearings in the case of most principal sanctions whereas the latter only speaks to an obligation to provide notice and a reasonable opportunity to respond. Only with respect to civil money penalties (under Section 1846 of the Act) and principal sanctions (under CLIA) in cases that do not pose immediate jeopardy, do the statutes require prior hearings, and these regulations reflect that mandate.

2. *Comment:* Many commenters requested that the list of initial determinations (§ 493.1844(c)) that are appealable be broadened.

Response: We have developed the regulatory list of initial determinations to be consistent with our treatment of other providers and suppliers under Medicare. We have provided for appeals wherever such opportunity is afforded other providers and suppliers. We have not granted appeal rights that would give laboratories rights broader or more numerous than are available to other Medicare providers and suppliers.

3. *Comment:* Several commenters requested that we develop an expedited hearing process for laboratories, stating that patient access to laboratory testing would be compromised if laboratories had to wait for more than 30 days for a hearing. One commenter stated that hearings should be expedited when a laboratory is determined to have an immediate and serious threat deficiency, in order to reclassify this determination to avoid closure of the laboratory.

Response: Hearings on HCFA determinations that affect a laboratory's status under CLIA or in the Medicare program are conducted by the Departmental Appeals Board. The burdens on the Board may be vastly increased by the CLIA enforcement provided for in this regulation. Moreover, many other factors, including the number of cases for other parties awaiting a hearing at any given time, determine how quickly each case is heard. The inclusion in these regulations of a provision for an expedited hearing process would therefore be impossible.

We realize that a laboratory's failure to make corrections very quickly in immediate jeopardy situations will trigger the suspension or limitation of the laboratory's CLIA certificate, thus causing full or partial closure of the facility. However, as noted above, the imposition of these sanctions before a hearing in immediate jeopardy situations is clearly authorized by section 353(i)(2) of the PHS Act. If laboratories are concerned with maintaining access to testing, they should focus all efforts on the expedited correction of their deficiencies, and not the receipt of an "expedited" hearing, by which we assume the commenters mean a hearing before the adverse action is taken. But conducting hearings within the 5 days before principal sanctions become effective in immediate jeopardy situations would be virtually impossible. When there are life-threatening deficiencies, action must be taken no later than this.

4. *Comment:* A few commenters expressed support for sanctioning a noncomplying laboratory before a hearing.

Response: We appreciate the support we have received for this rule and are committed to the development of regulations that reflect the enforcement-related aspects of the CLIA provisions

and that will effectively implement the law.

5. *Comment:* Ten commenters requested that a pre-hearing/pre-sanction mechanism be implemented for the laboratory to informally review and respond to inspection findings and/or certifications of noncompliance. Several of these commenters also stated that HCFA needs to clarify what is meant by the "opportunity to respond" at § 493.1810(b).

Response: Under Medicare, laboratories have always had numerous opportunities to challenge surveyors' findings throughout the inspection process, including during the actual inspection, at the exit conference, after receipt of the official statement of deficiencies and notice of sanction, and through a dialogue with survey agency staff and HCFA regional office personnel. This informal review mechanism, which constitutes the "opportunity to respond" is now available to all laboratories under CLIA. However, the use of this process will not delay the implementation of any sanction unless the laboratory either corrects the deficiencies within the 5-day or 15-day notice period or presents credible evidence to convince HCFA that a deficiency did not exist and should not have been cited. We have delineated the steps which a laboratory must take in responding to the proposed imposition of sanctions (the opportunity to respond) at § 493.1810(b).

6. *Comment:* Two commenters requested that judicial review be available for prospective and sanctioned laboratories. One of these commenters requested that HCFA delay the imposition of any alternative sanction until after completion of civil action.

Response: The right to judicial review, as specified in § 493.1844(g)(3), reflects the provision of both the Social Security Act and the PHS Act. Neither statute grants the right to judicial review to prospective laboratories. Neither law grants the right to judicial review of the imposition of any alternative sanction except civil money penalty. In those cases in which judicial review is authorized by law, it is available only after an ALJ hearing. It cannot and should not delay imposition of sanctions. To permit a noncomplying laboratory to continue to operate until all appeals were exhausted would be dangerous to the health and safety of the individuals served by the laboratory. It would also be inconsistent with the requirement of section 1846(b) of the Act, which requires the Secretary to minimize the time between the identification of violations and the imposition of sanctions.

I. Laboratory Registry (§ 493.1850)

1. *Comment:* The comments summarized below were received from 8 commenters in response to our request for suggestions of additional information that could be included in the Registry to help physicians and the public evaluate the performance of laboratories.

- Explain the meaning of the various actions taken by HCFA and identify the timeframe and type of deficiency for which a laboratory was cited.
- Include the outcome of all appealed decisions.
- Describe the methodology used to collect and prepare information for the Registry, as well as its uses and limitations.
- Include the same level of detail as is provided in the directed plan or correction.
- Publish the Registry in a form that physicians and clients can purchase if they wish.
- Consult with the industry in drafting explanations.
- Make clear when violations are relatively minor and identify situations in which the patient's health was not at risk.
- Allow laboratories to include their own explanatory information in a format established by HCFA.

The commenters also expressed concern and raised questions as follows:

- How will the information be "made available"? Will physicians and the public be informed when the Registry is available, or will copies be sent to physicians and other individuals?
- Will the information remain in the Registry for more than one year or will each edition list only the information from the preceding year?
- One commenter was concerned that the proposed rule did not require that a laboratory be given notice that it will be included in the registry and an opportunity to correct any error there might be as to whether the laboratory should be included or as to what sanctions were imposed.
- One commenter was of the opinion that the Registry was a good idea and would provide information that would enable patients to make appropriate decisions about the continued use of a laboratory.

Response: We appreciate the commenters' recommendations. We will add to the Registry information on the effective date of sanction and the date of the laboratory's verified compliance. We will also publish a list of all appealed decisions and corrections of erroneous information included in the previous year's Registry.

We believe any greater specificity in regulations is not appropriate at this time. After we have gained more experience in collecting and disseminating this information we will consider collecting and disseminating additional data as long as they are not too burdensome to maintain. The registry will include appropriate explanatory information to aid in the interpretation of the data. However, we simply cannot allow each laboratory to compose its own explanatory material prior to publication because of the enormity of the task of obtaining the information and editing it to meet length and format requirements. However, as stated in § 493.1850(a)(4), included in the list of laboratories on which alternative sanctions have been imposed will be any evidence of corrective action taken by the laboratory.

In response to the commenter who is unclear about how long the information will remain in the registry, as stated in § 493.1850(b), the laboratory registry is compiled for the calendar year preceding the date the information is made available.

2. *Comment:* Several commenters believed the name of a laboratory should not be included in the laboratory registry until the result of an administrative appeal is final.

Response: We acknowledge that there is a significant amount of concern among the commenters with respect to publishing information about sanctioned laboratories possibly before a hearing decision has been rendered. Nevertheless, HCFA is concerned about the difficulty the Department of Health and Human Services has encountered in bringing enforcement actions in the past, and, in particular, is concerned about cases remaining in litigation for months or years while substantial violations remain uncorrected. If there are condition-level deficiencies, HCFA will impose a sanction or sanctions, and will do so prior to a hearing in most cases, to minimize the time lapse between identification of the violations and imposition of the sanctions. This timely action is required by section 1846(b)(3) of the Act and is achievable because, with the exception of civil money penalties and principal sanctions imposed in non-immediate and serious threat cases, hearings need not be held before the imposition of the sanction. Section 353(n) of the PHS Act requires the publication of a list of the laboratories against which sanctions have been imposed, and in many instances the law allows us to impose sanctions before a hearing.

3. *Comment:* Several commenters requested a mechanism for correction of mistakes in the laboratory registry (both prior to and subsequent to publication). One commenter suggested we share a draft of the laboratory registry with all laboratories to be included in the registry to ensure that the information is accurate and no mistakes have been made. Another commenter believes State hospital associations should have access to the data prior to its release.

Response: It would be impossible for us to meet our statutory deadlines for publication of the Registry were we to share proposed Registry entries with individual laboratories. This is particularly true because of the huge universe of laboratories subject to CLIA, and the consequent possibility that a large number of them will be sanctioned at the same time. To safeguard against erroneous inclusion of the names of laboratories or individuals in the annual registry, prior to publication the HCFA regional offices will review their portions of the registry for verification of information. We believe this procedure should virtually prevent inaccurate reporting. However, if erroneous information is published, this information will be corrected in the next registry.

4. *Comment:* Several commenters were entirely opposed to the laboratory registry. They believe the public will be misled and only marginally served. In addition, they believe that a laboratory's credibility, once lost though inclusion on the registry, can never be regained.

Response: The laboratory registry is required by section 353(n) of the PHS Act. Moreover, we believe that the laboratory registry will provide a worthwhile service to physicians and the general public.

5. *Comment:* Two commenters suggested that there should be a registry of CLIA certified laboratories instead of a registry of sanctioned laboratories.

Response: We appreciate this comment: However, we believe the objective of the laboratory registry is to provide physicians and the general public specific information that is useful in evaluating the performance of the laboratories. If anyone is interested in knowing which laboratories in the State are certified as meeting CLIA requirements, he or she should contact the appropriate State agency or HCFA regional office.

6. *Comment:* A few commenters were of the opinion that the Registry should not include laboratories with condition level deficiencies that do not pose immediate jeopardy. Another thought that laboratories subject to the "directed plan of correction" sanction or submission of a correction schedule should not be included because by the time the Registry is published, the corrections would have been completed. A few commenters recommended that only laboratories which did not correct deficiencies within 12 months be included in the Registry.

Response: Section 353(n) of the PHS Act requires the Secretary to publish a list of laboratories against which enforcement sanctions have been imposed. While a directed plan of correction is considered an alternative sanction, a correction schedule developed by the laboratory is not an alternative sanction, and when not paired with an alternative sanction, would not be subject to publication in the registry. The PHS Act does not authorize us to exclude from the Registry any laboratories that have been sanctioned.

7. *Comment:* Two commenters suggested that instructions accompany the laboratory registry with background material on the method that was used to prepare the registry as well as a guide that outlines the uses and limitations of the information. One of the commenters stated that the instructions should mention that the Federal government tends to measure a laboratory's overall performance capabilities, but does not reflect actual outcomes. They also believe the Registry should note that an adverse action taken due to a laboratory's failure to comply with Federal requirements does not necessarily mean that the quality of the laboratory's tests was poor.

Response: We have not yet established the administrative procedures by which the Registry will be compiled and disseminated. Nor have we developed a format for the Registry. While we believe that the Registry will be published with some general explanatory material, the extent of that information is unknown at this time. We can say at this time that, in the case of laboratories the Federal government tends to measure overall capabilities (i.e., the laboratory's capability to conduct accurate and reliable testing) rather than actual outcomes, which would be impossible to measure for many laboratories. This is contrary to recent trends in the survey and certification program for other facility types. In the case of laboratories, however, the assumption must be made that if process requirements under CLIA are followed, the outcome will be positive (i.e., accurate and reliable test results Regarding the rationale for the imposition of adverse actions, we cannot say that noncompliance with Federal requirements and resulting adverse action always necessarily means that the quality of laboratory testing was poor. In fact, poor quality of laboratory testing is the presumption when deficiencies in the testing process, quality assurance, quality control, and other conditions are found, remain uncorrected, and lead to adverse actions.

8. *Comment:* One commenter suggested that dentists be identified in the final rule as recipients of the Registry.

Response: The Registry will be available to anyone who is interested, as indicated by the term "general public". To list specific individuals might give the impression of limitations that do not exist.

9. *Comment:* One commenter suggested that if the Federal government is to publish the names of laboratories involved in false billing, fraud and kickbacks, it should publish similar information about physician and corporate users of the laboratory.

Response: Because section 353(n) focuses the Registry on sanctioned laboratories, we cannot follow the commenter's suggestion since it would entail adding to the Registry persons or entities that either are not laboratories or are not laboratories that have been subject to the sanctions provided by CLIA.

10. *Comment:* One commenter requested that the names of individuals who are identified as needing training or technical assistance as part of a laboratory's plan or correction, not be released in the Registry in order to avoid the risk of slander charges. The commenter also suggested that the names of laboratory instruments not be released lest the Registry become a source of information to competitors.

Response: Nothing in the law or regulations requires or prohibits the release of this information.

IV. Summary of Changes from the Proposed Rule

A. Definitions.

1. We have consolidated all definitions for this part at § 493.2.

2. Revised definitions: "Condition level requirement and condition-level deficiency", "HCFA agent", "Immediate jeopardy"

3. *Added definitions:* "Adverse action", "Credible allegation of compliance", "Intentional violation", "Operator", "Owner", "Principal sanction", "State-exempt laboratory", "Unsuccessful participation in proficiency testing".

B. Imposition of Sanctions

1. Clarify the basis for imposition of sanctions. (§ 493.1804(b))

2. Explain why HCFA does not impose alternative sanctions on laboratories with certificates of waiver (§§ 493.1804(c) and 493.1806(c))

3. Clarify the meaning of "repeat" deficiencies. (§§ 493.1804(d) and 493.1834(d)(1))

4. Make clear that HCFA may bring civil suit against any laboratory, including one that is State-exempt. (§§ 493.1806(d), 493.1812(c) and 493.1846)

5. Remove proposed alternative sanction to require refund of Medicare payments for services furnished while any other alternative sanction was in effect. (Removal of §§ 493.1807(b)(3), 493.1830, and 493.1842(a)(1)(iii))

6. Provide for—

Including in the notice of sanction a statement as to the rationale for the sanction; and

Giving the laboratory formal acknowledgement of any evidence or other information it submits in response to the notice of sanction. (§ 493.1810(c)(1))

7. Provide for earlier lifting of a sanction if the laboratory can show that it achieved compliance before the date of revisit. (paragraph (e) added to § 493.1810; § 493.1820(b))

8. Clarify that HCFA may later revoke a CLIA certificate that it has suspended or limited because the deficiencies posed immediate jeopardy. (§ 493.1812(b))

9. Clarify that HCFA may impose a principal sanction when deficiencies are at the condition level but do not pose immediately jeopardy. (§ 493.1814(a)(2))

10. Make clear that, in connection with suspension of all or part of Medicare payments, the laboratory's agreement must include not charging the beneficiary's private insurance carrier. (§§ 493.1826(a)(1)(ii) and 493.1828(a)(2)(ii))

11. Include information about the nature of the non-compliance in the notice to the clients of a sanctioned laboratory. (§ 493.1832(b)(2))

12. Specify limitations on authority of State monitor. (§ 493.1836(a)(1))

C. Civil Money Penalty

1. Clarify duration of penalty. (§ 493.1834(f)(2))

2. Clarify that, if the laboratory requests a hearing, the civil money penalty is imposed only if the hearing decision upholds the imposition. (§ 493.1834(g)(1)(ii))

3. Specify the basis for computing interest. (§ 493.1834(i)(1)(ii))

D. Appeals Procedures

1. Clarify definition of "prospective laboratory". (§ 493.1844(a))

2. Clarify grounds for suspending or limiting a CLIA certificate before a hearing or hearing decision. (§ 493.1844(e)(2)(ii)(B))

3. Clarify that, if an ALJ decision upholds a suspension imposed because of immediate jeopardy, the suspension becomes a revocation. (§ 493.1844(e)(4)(ii))

4. Clarify that, for prospective laboratories, request for reconsideration is the required first step in the appeals process. (§ 493.1844(f)(1))

5. Remove references to appeals procedures for determinations that affect participation in the Medicare program with respect to sanctions imposed by the OIG. (§§ 493.1844(b)(1)(ii) and (b)(5))

6. Provide that hearings for laboratories facing principal or alternative sanctions will be conducted by the Departmental Appeals Board. (§493.1844(a)(2))

E. Laboratory Registry

1. Clarify the information to be included for laboratories on which HCFA has imposed alternative sanction. (§ 493.1850(a)(4))

2. Specify that each registry will include correction of errors in the previous registry. (§ 493.1850(c))

F. Notification of Clients

1. Clarify that the notification of noncompliance to a laboratory's clients is discretionary with HCFA. (§ 493.1832(b)(2)(ii))

V. Regulatory Impact Analysis

A. Executive Order 12291 and Regulatory Flexibility Act

The Regulatory Impact Analysis contained in HSQ–176–FC, published elsewhere in this issue of the **Federal Register**, addresses the impact of the entire CLIA program. Regarding this regulation specifically, we see no reason why the enforcement procedures, as such, would have a significant effect on laboratories independent of the other effects of the CLIA reform. Presumably, some laboratories will fail to meet CLIA standards and will face sanctions. A few will be put out of business. But the cause of this will be the substantive standards themselves, not the details of the sanctions procedures. Indeed, the cost of implementing the enforcement procedures will likely involve only a few million dollars a year (in marked contrast to such other elements of CLIA as inspection procedures). Likewise, there do not appear to be enforcement options which would significantly affect the cost of the procedures.

B. Executive Order 12612

Under Executive Order 12612, "Federalism," we must prepare a Federalism Assessment for any action that may have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. The enforcement system to be imposed under CLIA 88, will have a substantial effect on the relationship between the Federal government and the States in the area of clinical laboratory regulation.

Until passage of this statute, the Federal government regulated about 13,000 clinical laboratories, mainly those engaged in interstate commerce or based in hospitals participating in Medicare. The much more numerous intrastate laboratories, including those located in physician's offices, were in many, though not all cases, regulated by the States. CLIA 88 does not preclude continued State regulation and licensure. It allows HCFA to accept results of inspections performed by State licensure agencies (as well as private non-profit organizations) in lieu of meeting CLIA requirements or as proof that the laboratory can be deemed to meet requirements for a CLIA certificate. (See our proposed rule: Clinical Laboratories Improvement Act Programs; Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and State Licensure Agencies, published August 20, 1990 at 55 FR 33936). However, a realistic appraisal suggests that except for those States electing to operate within a narrowly circumscribed Federal framework, and except for the essential function of personnel licensure which is left almost entirely to the States, there will be little of the former role for States in laboratory regulation remaining under CLIA 88.

Under the regulations referred to in the preceding paragraph:

- States may be relieved of the responsibility for licensure of their laboratories but may choose to exercise such responsibility and authority at their option; and
- States approved by HCFA for exemption of their laboratories from CLIA requirements may impose user fees on the laboratories they inspect.

The Assistant Secretary for Planning and Evaluation, the designated official under the Executive Order, certifies that this rule has been assessed in light of

the principles, criteria, and requirements stated in the Executive Order.

VI. Paperwork Reduction Act

Sections 493.1810(b), 493.1816(a), 493.1820(d), and 493.1832(b) of this rule contain information collection requirements that are subject to OMB review under the Paperwork Reduction Act of 1980. These reporting and recordkeeping requirements are not effective until cleared by the Office of Management and Budget.

Public reporting burden for these requirements is estimated as follows:

- For preparation of written evidence against the imposition of sanctions—5 hours;
- For preparation of a plan of correction—5 hours;
- For preparation of a revised plan of correction—3 hours; and
- For completion of a list of laboratory clients—1 hour.

These estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

If you comment on this burden estimate or any other aspect of these collection of information requirements, including suggestions for reducing the burden, please send copies directly to Office of Financial Management, HCFA, P.O. Box 26684, Baltimore, Maryland 21207, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, Attention: Allison Herron Eydt, HCFA Desk Officer. A notice will be published in the **Federal Register** when approval is obtained.

VII. List of Subjects in 42 CFR Part 493

Health facilities, Laboratories, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR chapter IV would be amended as set forth below.

A. The authority citation for part 493 continues to read as follows:

Authority: Sec. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following 11861(s)(11), 1861(s)(12), 1861(s)(13), 1861(s)(14), 1861(s)(15), and 1861(s)(16) of the Social Security Act (42 U.S.C. 1302, 1395–(e), the sentence following 1395x (s)(11), 1395x (s)(12), 1395x (s)(13), 1395x (s)(14), 1395x (s)(15), and 1395x (s)(16)).

B. In § 493.2 the introductory text is revised the following definitions are added in alphabetical order and the definitions for *State-exempt laboratory* is revised and placed in alphabetical order:

§ 493.2 Definitions.

As used in this part, unless the context indicates otherwise—

* * * * *

Adverse action means the imposition of a principal or alternative sanction by HCFA.

ALJ stands for Administrative Law Judge.

Alternative sanctions means sanctions that may be imposed in lieu of or in addition to principal sanctions. The term is synonymous with "intermediate sanctions" as used in section 1846 of the Act.

* * * * *

CLIA certificate means any of the following types of certificates issued by HCFA or its agent:

(1) *Certificate* means a certificate issued to a laboratory after an inspection that finds the laboratory to be in compliance with all condition level requirements.

(2) *Certificate of accreditation* means a certificate issued on the basis of the laboratory's accreditation by an accreditation organization approved by HCFA, indicating that the laboratory is deemed to meet CLIA requirements.

(3) *Certificate of registration or registration certificate* means a certificate issued to an entity that is not qualified to receive a certificate of waiver, to enable the entity to conduct laboratory testing until the entity is determined to be in compliance through an inspection by HCFA, the State, or a HCFA agent, or is accredited by an approved accreditation organization.

(4) *Certificate of waiver* means a certificate issued to a laboratory to perform only waiver tests, that are described in § 493.15(b).

Condition level deficiency means noncompliance with one or more condition level requirements.

Condition level requirements means any of the requirements identified as "conditions" in subparts G through Q of this part.

Credible allegation of compliance means a statement or documentation that—

(1) Is made by a representative of a laboratory that has a history of having maintained a commitment to compliance and of taking corrective action when required;

(2) Is realistic in terms of its being possible to accomplish the required corrective action between the date of the exit conference and the date of the allegation; and

(3) Indicates that the problem has been resolved.

HCFA's agent means an entity with which HCFA arranges to inspect laboratories and assess laboratory activities against CLIA conditions, and which may be a State survey agency, a professional organization, a component of the Department, or any other group that HCFA approves for this purpose. The State survey agency may not be HCFA's agent in a State in which all laboratories are exempt from CLIA requirements because HCFA has approved the State's licensure program.

* * * * *

Immediate jeopardy means a situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public. This term is synonymous with imminent and serious risk to human health and significant hazard.

Intentional violation means knowing and willful noncompliance with any CLIA condition.

* * * * *

Operator means the individual or group of individuals who oversee all facets of the operation of a laboratory and who bear primary responsibility for the safety and reliability of the results of all specimen testing performed in that laboratory. The term includes—

(1) A director of the laboratory if he or she meets the stated criteria; and

(2) The members of the board of directors and the officers of a laboratory that is a small corporation under subchapter S of the Internal Revenue Code.

Owner means any person who owns any interest in a laboratory except for an interest in a laboratory whose stock and/or securities are publicly traded. (That is e.g., the purchase of shares of stock or securities on the New York Stock Exchange in a corporation owning a laboratory would not make a person an owner for the purpose of this regulation.)

Party means a laboratory affected by any of the enforcement procedures set forth in this subpart, or HCFA or the OIG, as appropriate.

* * * * *

Principal sanction means the suspension, limitation, or revocation of any type of CLIA certificate or the cancellation of the laboratory's approval to receive Medicare payment for its services.

Prospective laboratory means a laboratory that is operating under a registration certificate or is seeking any

of the three other types of CLIA certificates.

* * * * *

State-exempt laboratory means a laboratory that does not require a CLIA certificate because it is licensed by a State whose licensure program has been approved by HCFA.

* * * * *

Unsuccessful participation in proficiency testing means any of the following:

(1) Unsatisfactory performance for the same analyte in two consecutive or two out of three testing events.

(2) Repeated unsatisfactory overall testing event scores for two consecutive or two out of three testing events for the same specialty or subspecialty.

(3) An unsatisfactory testing event score for those subspecialties not graded by analyte (that is, bacteriology, micobacteriology, virology, parasitology, mycology, blood compatibility, immunohematology, or syphilis serology) for the same subspecialty for two consecutive or two out of three testing events.

(4) Failure of a laboratory performing gynecologic cytology to meet the standard at § 493.855.

C. A new subpart R is added to part 493, to read as follows:

PART 493—LABORATORY REQUIREMENTS

Subpart R—Enforcement Procedures

Sec.

493.1800 Basis and scope.
493.1804 General considerations.
493.1806 Available sanctions: All laboratories.
493.1807 Additional sanctions: Laboratories that participate in Medicare.
493.1808 Adverse action on any type of CLIA certificate: Effect on Medicare approval.
493.1809 Limitation on Medicaid payment.
493.1810 Imposition and lifting of alternative sanctions.
493.1812 Action when deficiencies pose immediate jeopardy.
493.1814 Action when deficiencies are at the condition level but do not pose immediate jeopardy.
493.1816 Action when deficiencies are not at the condition level.
493.1820 Ensuring timely correction of deficiencies.
493.1826 Suspension of part of Medicare payments.
493.1828 Suspension of all Medicare payments.
493.1832 Directed plan of correction and directed portion of a plan of correction.
493.1834 Civil money penalty.
493.1836 State onsite monitoring.
493.1838 Training and technical assistance for unsuccessful participation in proficiency testing.
493.1840 Suspension, limitation, or revocation of any type of CLIA certificate.
493.1842 Cancellation of Medicare approval.
493.1844 Appeals procedures.
493.1846 Civil action.
493.1850 Laboratory registry.

Subpart R—Enforcement Procedures

§ 493.1800 Basis and scope.

(a) *Statutory basis.* (1) Section 1846 of the Act—

(i) Provides for intermediate sanctions that may be imposed on laboratories that perform clinical diagnostic tests on human specimens when those laboratories are found to be out of compliance with one or more of the conditions for Medicare coverage of their services; and

(ii) Requires the Secretary to develop and implement a range of such sanctions, including four that are specified in the statute.

(2) The Clinical Laboratories Improvement Act of 1967 (section 353 of the Public Health Service Act) as amended by CLIA '88—

(i) Establishes requirements for all laboratories that perform clinical diagnostic tests on human specimens;

(ii) Requires a Federal certification scheme to be applied to all such laboratories; and

(iii) Grants the Secretary broad enforcement authority, including—

(A) Use of intermediate sanctions;

(B) Suspension, limitation, or revocation of the certificate of a laboratory that is out of compliance with one or more requirements for a certificate; and

(C) Civil suit to enjoin any laboratory activity that constitutes a significant hazard to the public health.

(3) Section 353 also—

(1) Provides for imprisonment or fine for any person convicted of intentional violation of CLIA requirements;

(ii) Specifies the administrative hearing and judicial review rights of a laboratory that is sanctioned under CLIA; and

(iii) Requires the Secretary to publish annually a list of all laboratories that have been sanctioned during the preceding year.

(b) *Scope and applicability.* This subpart sets forth—

(1) The policies and procedures that HCFA follows to enforce the requirements applicable to laboratories under CLIA and under section 1846 of the Act; and

(2) The appeal rights of laboratories on which HCFA imposes sanctions.

§ 493.1804 General considerations.

(a) *Purpose.* The enforcement mechanisms set forth in this subpart have the following purposes:

(1) To protect all individuals served by laboratories against substandard testing of specimens.

(2) To safeguard the general public against health and safety hazards that might result from laboratory activities.

(3) To motivate laboratories to comply with CLIA requirements so that they can provide accurate and reliable test results.

(b) *Basis for decision to impose sanctions.* (1) HCFA's decision to impose sanctions is based on one or more of the following:

(i) Deficiencies found by HCFA or its agents in the conduct of inspections to certify or validate compliance with Federal requirements, or through review of materials submitted by the laboratory (e.g., personnel qualifications).

(ii) Unsuccessful participation in proficiency testing.

(2) HCFA imposes one ore more of the alternative or principal sanctions specified in § 493.1806 and § 493.1807 when HCFA or HCFA's agent finds that a laboratory has condition-level deficiencies.

(c) *Imposition of alternative sanctions.* (1) HCFA may impose alternative sanctions in lieu of the principal sanctions, (HCFA does not impose alternative sanctions on laboratories that have certificates of waiver because those laboratories are not inspected for compliance with condition-level requirements.)

(2) HCFA may impose alternative sanctions other than a civil money penalty after the laboratory has had an opportunity to respond, but before the hearing specified in § 493.1844.

(d) *Choice of sanction: Factors considered.* HCFA bases its choice of sanction or sanctions on consideration of one or more factors that include, but are not limited to, the following, as assessed by the State or by HCFA, or its agents:

(1) Whether the deficiencies pose immediate jeopardy.

(2) The nature, incidence, severity, and duration of the deficiencies or noncompliance.

(3) Whether the same condition level deficiencies have been identified repeatedly.

(4) The accuracy and extent of laboratory records (e.g., of remedial action) in regard to the noncompliance, and their availability to the State, to other HCFA agents, and to HCFA.

(5) The relationship of one deficiency or group of deficiencies to other deficiencies.

(6) The overall compliance history of the laboratory including but not limited to any period of noncompliance that occurred between certifications of compliance.

(7) The corrective and long-term compliance outcomes that HCFA hopes to achieve through application of the sanction.

(8) Whether the laboratory has made any progress toward improvement following a reasonable opportunity to correct deficiencies.

(9) Any recommendation by the State agency as to which sanction would be appropriate.

(e) *Number of alternative sanctions.* HCFA may impose a separate sanction for each condition level deficiency or a single sanction for all condition level deficiencies that are interrelated and subject to correction by a single course of action.

(f) *Appeal rights.* The appeal rights of laboratories dissatisfied with the imposition of a sanction are set forth in § 493.1844.

§ 493.1806 Available sanctions: All laboratories.

(a) *Applicability.* HCFA may impose one or more of the sanctions specified in this section on a laboratory that is out of compliance with one or more CLIA conditions.

(b) *Principal sanction.* HCFA may impose any of the three principal CLIA sanctions, which are suspension, limitation, or revocation of any type of CLIA certificate.

(c) *Alternative sanctions.* HCFA may impose one or more of the following alternative sanctions in lieu of or in addition to imposing a principal sanction, except on a laboratory that has a certificate of waiver.

(1) Directed plan of correction, as set forth at § 493.1832.

(2) State onsite monitoring as set forth at § 493.1836.

(3) Civil money penalty, as set forth at § 493.1834.

(d) *Civil suit.* HCFA may bring suit in the appropriate U.S. District Court to enjoin continuation of any activity of any laboratory (including a State-exempt laboratory that has been found with deficiencies during a validation survey), if HCFA has reason to believe that continuation of the activity would constitute a significant hazard to the public health.

(e) *Criminal sanctions.* Under section 353(1) of the PHS Act, an individual who is convicted of intentionally violating any CLIA requirement may be imprisoned or fined.

§ 493.1807 Additional sanctions: Laboratories that participate in Medicare.

The following additional sanctions are available for laboratories that are out of compliance with one or more CLIA conditions and that have approval to receive Medicare payment for their services.

(a) *Principal sanction.* Cancellation of the laboratory's approval to receive Medicare payment for its services.

(b) *Alternative sanctions.* (1) Suspension of payment for tests in one or more specific specialties or subspecialties, performed on or after the effective date of sanction.

(2) Suspension of payment for all tests in all specialties and subspecialties performed on or after the effective date of sanction.

§ 493.1808 Adverse action on any type of CLIA certificate: Effect on Medicare approval.

(a) *Suspension or revocation of any type of CLIA certificate.* When HCFA suspends or revokes any type of CLIA certificate, HCFA concurrently cancels the laboratory's approval to receive Medicare payment for its services.

(b) *Limitation of any type of CLIA certificate.* When HCFA limits any type of CLIA certificate, HCFA concurrently limits Medicare approval to only those specialties or subspecialties that are authorized by the laboratory's limited certificate.

§ 493.1809 Limitation on Medicaid payment.

As provided in section 1902(a)(9)(C) of the Act, payment for laboratory services may be made under the State plan only if those services are furnished by a laboratory that meets CLIA conditions.

§ 493.1810 Imposition and lifting of alternative sanctions.

(a) *Notice of noncompliance and of proposed sanction: Content.* If HCFA or its agency identifies condition level noncompliance in a laboratory, HCFA or its agent gives the laboratory written notice of the following:

(1) The condition level noncompliance that it has identified.

(2) The sanction or sanctions that HCFA or its agent proposes to impose against the laboratory.

(3) The rationale for the proposed sanction or sanctions.

(4) The projected effective date and duration of the proposed sanction or sanctions.

(5) The authority for the proposed sanction or sanctions.

(6) The time allowed (at least 10 days) for the laboratory to respond to the notice.

(b) *Opportunity to respond.* During the period specified in paragraph (a)(6) of this section, the laboratory may submit to HCFA or its agent written evidence or other information against the imposition of the proposed sanction or sanctions.

(c) *Notice of imposition of sanction—*(1) *Content.* HCFA gives the laboratory written notice that acknowledges any evidence or information received from the laboratory and specifies the following:

(i) The sanction or sanctions to be imposed against the laboratory.

(ii) The authority and rationale for the imposing sanction or sanctions.

(iii) The effective date and duration of sanction.

(2) *Timing.* (i) If HCFA or its agent determines that the deficiencies pose immediate jeopardy, HCFA provides notice at least 5 days before the effective date of sanction.

(ii) If HCFA or its agent determines that the deficiencies do not pose immediate jeopardy, HCFA provides notice at least 15 days before the effective date of the sanction.

(d) *Duration of alternative sanctions.* An alternative sanction continues until the earlier of the following occurs:

(1) The laboratory corrects all condition level deficiencies.

(2) HCFA's suspension, limitation, or revocation of the laboratory's CLIA certificate becomes effective.

(e) *Lifting of alternative sanctions—*(1) *General rule.* Alternative sanctions are not lifted until a laboratory's compliance with all condition level requirements is verified.

(2) *Credible allegation of compliance.* When a sanctioned laboratory submits a credible allegation of compliance, HCFA's agent determines whether—

(i) It can certify compliance on the basis of the evidence presented by the laboratory in its allegation; or

(ii) It must revisit to verify whether the laboratory has, in fact, achieved compliance.

(3) *Compliance achieved before the date of revisit.* If during a revisit, the laboratory presents credible evidence (as determined by HCFA or its agent) that it achieved compliance before the date of revisit, sanctions are lifted as of that earlier date.

§ 493.1812 Action when deficiencies pose immediate jeopardy.

If a laboratory's deficiencies pose immediate jeopardy, the following rules apply:

(a) HCFA requires the laboratory to take immediate action to remove the jeopardy and may impose one or more alternative sanctions to help bring the laboratory into compliance.

(b) If the findings of a revisit indicate that a laboratory has not eliminated the jeopardy, HCFA suspends or limits the laboratory's CLIA certificate no earlier than 5 days after the date of notice of suspension or limitation. HCFA may later revoke the certificate.

(c) In addition, if HCFA has reason to believe that the continuation of any activity by any laboratory (either the entire laboratory operation or any specialty or subspecialty of testing) would constitute a significant hazard to the public health, HCFA may bring suit and seek a temporary injunction or restraining order against continuation of that activity by the laboratory, regardless of the type of CLIA certificate the laboratory has and of whether it is State-exempt.

§ 493.1814 Action when deficiencies are at the condition level but do not pose immediate jeopardy.

If a laboratory has condition level deficiencies that do not pose immediate jeopardy, the following rules apply:

(a) *Initial action.* (1) HCFA may cancel the laboratory's approval to receive Medicare payment for its services.

(2) HCFA may suspend, limit, or revoke the laboratory's CLIA certificate.

(3) If HCFA does not impose a principal sanction under paragraph (a)(1) or (a)(2) of this section, it imposes one or more alternative sanctions. In the case of unsuccessful participation in proficiency testing, HCFA may impose the training and technical assistance requirement set forth at § 493.1838 in lieu of, or in addition to, one or more alternative sanctions.

(b) *Failure to correct condition level deficiencies.* If HCFA imposes alternative sanctions for condition level deficiencies that do not pose immediate jeopardy, and the laboratory does not correct the condition level deficiencies within 12 months after the last day of inspection, HCFA—

(1) Cancels the laboratory's approval to receive Medicare payment for its services, and discontinues the Medicare payment sanctions as of the day cancellation is effective.

(2) Following a revisit which indicates that the laboratory has not corrected its condition level deficiencies, notifies the laboratory that it proposes to suspend, limit, or revoke the certificate, as specified in § 493.1816(b), and the laboratory's right to hearing; and

(3) May impose (or continue, if already imposed) any alternative sanctions that do not pertain to Medicare payments. (Sanctions imposed under the authority of section 353 of the PHS Act may continue for more than 12 months from the last date of inspection, (while a hearing on the proposed suspension, limitation, or revocation of the certificate, registration certificate, or certificate of accreditation is pending.)

(c) *Action after hearing.* If a hearing decision upholds a proposed suspension, limitation, or revocation of a laboratory's CLIA certificate, HCFA discontinues any alternative sanctions as of the day it makes the suspension, limitation, or revocation effective.

§ 493.1816 Action when deficiencies are not at the condition level.

If a laboratory has deficiencies, that are not at the condition level, the following rules apply:

(a) *Initial action.* The laboratory must submit a plan of correction that is acceptable to HCFA in content and time frames.

(b) *Failure to correct deficiencies.* If, on revisit, it is found that the laboratory has not corrected the deficiencies within 12 months after the last day of inspection, the following rules apply:

(1) HCFA cancels the laboratory's approval to receive Medicare payment for its services.

(2) HCFA notifies the laboratory of its intent to suspend, limit, or revoke the laboratory's CLIA certificate and of the laboratory's right to a hearing.

§ 493.1820 Ensuring timely correction of deficiencies.

(a) *Timing of visits.* HCFA, the State survey agency or other HCFA agent may visit the laboratory at any time to evaluate progress, and at the end of the period to determine whether all corrections have been made.

(b) *Deficiencies corrected before a visit.* If during a visit, a laboratory produces credible evidence that it achieved compliance before the visit, the sanctions are lifted as of that earlier date.

(c) *Failure to correct deficiencies.* If during a visit it is found that the laboratory has not corrected its deficiencies, HCFA may propose to suspend, limit, or revoke the laboratory's CLIA certificate.

(d) *Additional time for correcting lower level deficiencies* not at the condition level. If at the end of the plan of correction period all condition level deficiencies have been corrected, and there are deficiencies, that are not at the condition level, HCFA may request a revised plan of correction. The revised plan may not extend beyond 12 months from the last day of the inspection that originally identified the cited deficiencies.

(e) *Persistence of deficiencies.* If at the end of the period covered by the plan of correction, the laboratory still has deficiencies, the rules of § 493.1814 and § 493.1816 apply.

§ 493.1826 Suspension of part of Medicare payments.

(a) *Application.* (1) HCFA may impose this sanction if a laboratory—

(i) Is found to have condition level deficiencies with respect to one or more specialties or subspecialties of tests; and

(ii) Chooses to agree (in return for not having its Medicare approval cancelled immediately) not to charge Medicare beneficiaries or their private insurance carriers for the services for which Medicare payment is suspended.

(2) HCFA suspends Medicare payment for those specialities or subspecialties of tests for which the laboratory is out of compliance with Federal requirements.

(b) *Procedures.* Before imposing this sanction, HCFA provides notice of sanction and opportunity to respond in accordance with § 493.1810.

(c) *Duration and effect of sanction.* This sanction continues until the laboratory corrects the condition level deficiencies or HCFA cancels the laboratory's approval to receive Medicare payment for its services, but in no event longer than 12 months.

(1) If the laboratory corrects all condition level deficiencies, HCFA resumes Medicare payment effective for all services furnished on or after the date the deficiencies are corrected.

§ 493.1828 Suspension of all Medicare payments.

(a) *Application.* (1) HCFA may suspend payment for all Medicare-approved laboratory services when the laboratory has condition level deficiencies.

(2) HCFA suspends payment for all Medicare covered laboratory services when the following conditions are met:

(i) Either—

(A) The laboratory has not corrected its condition level deficiencies included in the plan of correction within 3 months from the last date of inspection; or

(B) The laboratory has been found to have the same condition level deficiencies during three consecutive inspections; and

(ii) The laboratory has chosen (in return for not having its Medicare approval immediately cancelled), to not charge Medicare beneficiaries or their

private insurance carriers for services for which Medicare payment is suspended.

(3) HCFA suspends payment for services furnished on and after the effective date of sanction.

(b) *Procedures.* Before imposing this sanction, HCFA provides notice of sanction and opportunity to respond in accordance with § 493.1810.

(c) *Duration and effect of sanction.* (1) Suspension of payment continues until all condition level deficiencies are corrected, but never beyond twelve months.

(2) If all the deficiencies are not corrected by the end of the 12 month period, HCFA cancels the laboratory's approval to receive Medicare payment for its services.

§ 493.1832 Directed plan of correction and directed portion of a plan of correction.

(a) *Application.* HCFA may impose a directed plan of correction as an alternative sanction for any laboratory that has condition level deficiencies. If HCFA does not impose a directed plan of correction as an alternative sanction for a laboratory that has condition level deficiencies, it at least imposes a directed portion of a plan of correction when it imposes any of the following alternative sanctions:

(1) State onsite monitoring.

(2) Civil money penalty.

(3) Suspension of all or part of Medicare payments.

(b) *Procedures*—(1) *Directed plan of correction.* When imposing this sanction, HCFA—

(i) Gives the laboratory prior notice of the sanction and opportunity to respond in accordance with § 493.1810;

(ii) Directs the laboratory to take specific corrective action within specific time frames in order to achieve compliance; and

(iii) May direct the laboratory to submit the names of laboratory clients for notification purposes, as specified in paragraph (b)(3) of this section.

(2) *Directed portion of a plan of correction.* HCFA may decide to notify clients of a sanctioned laboratory, because of the seriousness of the noncompliance (e.g., the existence of immediate jeopardy) or for other reasons. When imposing this sanction, HCFA takes the following steps—

(i) Directs the laboratory to submit to HCFA, the State survey agency, or other HCFA agent, within 10 calendar days after the notice of the alternative sanction, a list of names and addresses of all physicians, providers, suppliers, and other clients who have used some or all of the services of the laboratory since the last certification inspection or within any other timeframe specified by HCFA.

(ii) Within 30 calendar days of receipt of the information, may send to each laboratory client, via the State survey agency, a notice containing the name and address of the laboratory, the nature of the laboratory's noncompliance, and the kind and effective date of the alternative sanction.

(iii) Sends to each laboratory client, via the State survey agency, notice of the recission of an adverse action within 30 days of the rescission.

(3) *Notice of imposition of a principal sanction following the imposition of an alternative sanction.* If HCFA imposes a principal sanction following the imposition of an alternative sanction, and for which HCFA has already obtained a list of laboratory clients, HCFA may use that list to notify the clients of the imposition of the principal sanction.

(c) *Duration of a directed plan of correction.* If HCFA imposes a directed plan of correction, and on revisit it is found that the laboratory has not corrected the deficiencies within 12 months from the last day of inspection, the following rules apply:

(1) HCFA cancels the laboratory's approval for Medicare payment of its services, and notifies the laboratory of HCFA's intent to suspend, limit, or revoke the laboratory's CLIA certificate.

(2) The directed plan of correction continues in effect until the day suspension, limitation, or revocation of the laboratory's CLIA certificate.

§ 493.1834 Civil money penalty.

(a) *Statutory basis.* Sections 1846 of the Act and 353(h)(2)(B) of the PHS Act authorize the Secretary to impose civil money penalties on laboratories. Section 1846(b)(3) of the Act specifically provides that incrementally more severe fines may be imposed for repeated or uncorrected deficiencies.

(b) *Scope.* This section sets forth the procedures that HCFA follows to impose a civil money penalty in lieu of suspending, limiting, or revoking the certificate, registration certificate or certificate of accreditation of a laboratory that is found to have condition level deficiencies.

(c) *Basis for imposing a civil money penalty.* HCFA may impose a civil money penalty against any laboratory determined to have condition level deficiencies regardless of whether those deficiencies pose immediate jeopardy.

(d) *Amount of penalty*—(1) *Factors considered.* In determining the amount of the penalty, HCFA takes into account the following factors:

(i) The nature, scope, severity, and duration of the noncompliance.

(ii) Whether the same condition level deficiencies have been identified during three consecutive inspections.

(iii) The laboratory's overall compliance history including but not limited to any period of noncompliance that occurred between certifications of compliance.

(iv) The laboratory's intent or reason for noncompliance.

(v) The accuracy and extent of laboratory records and their availability to HCFA, the State survey agency, or other HCFA agent.

(2) *Range of penalty amount.*

(i) For a condition level deficiency that poses immediate jeopardy, the range is $3,050–$10,000 per day of noncompliance or per violation.

(ii) For a condition level deficiency that does not pose immediate jeopardy, the range is $50–$3,000 per day of noncompliance or per violation.

(3) *Decreased penalty amounts.* If the immediate jeopardy is removed, but the deficiency continues, HCFA shifts the penalty amount to the lower range.

(4) *Increased penalty amounts.* HCFA may, before the hearing, propose to increase the penalty amount for a laboratory that has deficiencies which, after imposition of a lower level penalty amount, become sufficiently serious to pose immediate jeopardy.

(e) *Procedures for imposition of civil money penalty*—(1) *Notice of intent.* (i) HCFA sends the laboratory written notice, of HCFA's intent to impose a civil money penalty.

(ii) The notice includes the following information:

(A) The statutory basis for the penalty.

(B) The proposed daily or per violation amount of the penalty.

(C) The factors (as described in paragraph (d)(1) of this section) that HCFA considered.

(D) The opportunity for responding to the notice in accordance with § 493.1810(c).

(E) A specific statement regarding the laboratory's appeal rights.

(2) *Appeal rights.* (i) The laboratory has 60 days from the date of receipt of the notice of intent to impose a civil money penalty to request a hearing in accordance with § 493.1844(g).

(ii) If the laboratory requests a hearing, all other pertinent provisions of § 493.1844 apply.

(iii) If the laboratory does not request a hearing, HCFA may reduce the proposed penalty amount by 35 percent.

(f) *Accrual and duration of penalty*—(1) *Accrual of penalty.* The civil money penalty begins accruing as follows:

(i) 5 days after notice of intent if there is immediate jeopardy.

(ii) 15 days after notice of intent if there is not immediate jeopardy.

(2) *Duration of penalty.* The civil money penalty continues to accrue until the earliest of the following occurs:

(i) The laboratory's compliance with condition level requirements is verified on the basis of the evidence presented by the laboratory in its credible allegation of compliance or at the time or revisit.

(ii) Based on credible evidence presented by the laboratory at the time of revisit, HCFA determines that compliance was achieved before the revisit. (In this situation, the money penalty stops accruing as of the date of compliance.)

(iii) HCFA suspends, limits, or revokes the laboratory's CLIA certificate, registration certificate, or certificate of accreditation.

(g) *Computation and notice of total penalty amount*— (1) *Computation.* HCFA computes the total penalty amount after the laboratory's compliance is verified or HCFA suspends, limits, or revokes the laboratory's CLIA certificate but in no event before—

(i) The 60 day period for requesting a hearing has expired without a request or the laboratory has explicitly waived its right to a hearing; or

(ii) Following a hearing requested by the laboratory, the ALJ issues a decision that upholds imposition of the penalty.

(2) *Notice of penalty amount and due date of penalty.* The notice includes the following information:

(i) Daily or per violation penalty amount.

(ii) Number of days or violations for which the penalty is imposed.

(iii) Total penalty amount.

(iv) Due date for payment of the penalty.

(h) *Due date for payment of penalty.* (1) Payment of a civil money penalty is due 15 days from the date of the notice specified in paragraph (g)(2) of this section.

(2) HCFA may approve a plan for a laboratory to pay a civil money penalty, plus interest, over a period of up to one year from the original due date.

(i) *Collection and settlement*—(1) *Collection of penalty amounts.* (i) The determined penalty amount may be deducted from any sums then or later owing by the United States to the laboratory subject to the penalty.

(ii) Interest accrues on the unpaid balance of the penalty, beginning on the due date. Interest is computed at the rate specified in § 405.376(d) of this chapter.

(2) *Settlement.* HCFA has authority to settle any case at any time before the ALJ issues a hearing decision.

§ 493.1836 State onsite monitoring.

(a) *Application.*

(1) HCFA may require continuous or intermittent monitoring of a plan of correction by the State survey agency to ensure that the laboratory makes the improvements necessary to bring it into compliance with the condition level requirements. (The State monitor does not have management authority, that is, cannot hire or fire staff, obligate funds, or otherwise dictate how the laboratory operates. The monitor's responsibility is to oversee whether corrections are made.)

(2) The laboratory must pay the costs of onsite monitoring by the State survey agency.

(i) The costs are computed by multiplying the number of hours of onsite monitoring in the laboratory by the hourly rate negotiated by HCFA and the State.

(ii) The hourly rate includes salary, fringe benefits, travel, and other direct and indirect costs approved by HCFA.

(b) *Procedures.* Before imposing this sanction, HCFA provides notice of sanction and opportunity to respond in accordance with § 493.1810.

(c) *Duration of sanction.* (1) If HCFA imposes onsite monitoring, the sanction continues until HCFA determines that the laboratory has the capability to ensure compliance with all condition level requirements.

(2) If the laboratory does not correct all deficiencies within 12 months, and a revisit indicates that deficiencies remain, HCFA cancels the laboratory's approval for Medicare payment for its services and notifies the laboratory of its intent to suspend, limit, or revoke the laboratory's certificate, registration certificate, or certificate of accreditation.

(3) If the laboratory still does not correct its deficiencies, the Medicare sanction continues until the suspension, limitation, or revocation of the laboratory's certificate, registration certificate, or certificate of accreditation is effective.

§ 493.1838 Training and technical assistance for unsuccessful participation in proficiency testing.

If a laboratory's participation in proficiency testing is unsuccessful, HCFA may require the laboratory to undertake training of its personnel, or to obtain necessary technical assistance, or both, in order to meet the requirements of the proficiency testing program. This requirement is separate from the principal and alternative sanctions set forth in §§ 493.1808 and 493.1807.

§ 493.1840 Suspension, limitation, or revocation of any type of CLIA certificate.

(a) *Adverse action based on actions of the laboratory's owner, operator or employees.* HCFA may initiate adverse action to suspend, limit or revoke any CLIA certificate if HCFA finds that a laboratory's owner or operator or one of its employees has—

(1) Been guilty of misrepresentation in obtaining a CLIA certificate;

(2) Performed, or represented the laboratory as entitled to perform, a laboratory examination or other procedure that is not within a category of laboratory examinations or other procedures authorized by its CLIA certificate;

(3) Failed to comply with the certificate requirements and performance standards;

(4) Failed to comply with reasonable requests by HCFA for any information or work on materials that HCFA concludes is necessary to determine the laboratory's continued eligibility for its CLIA certificate or continued compliance with performance standards set by HCFA;

(5) Refused a reasonable request by HCFA or its agent for permission to inspect the laboratory and its operation and pertinent records during the hours that the laboratory is in operation;

(6) Violated or aided and abetted in the violation of any provisions of CLIA and its implementing regulations;

(7) Failed to comply with an alternative sanction imposed under this subpart; or

(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked. (This provision applies only to the owner or operator, not to all of the laboratory's employees.)

(b) *Adverse action based on improper referrals in proficiency testing.* If HCFA determines that a laboratory has intentionally referred its proficiency testing samples to another laboratory for analysis, HCFA revokes the laboratory's CLIA certificate for at least one year, and may also impose a civil money penalty.

(c) *Adverse action based on exclusion from Medicare.* If the OIG excludes a laboratory from participation in Medicare, HCFA suspends the laboratory's CLIA certificate for the

period during which the laboratory is excluded.

(d) *Procedures for suspension or limitation*—(1) *Basic rule.* Except as provided in paragraph (d)(2) of this section, HCFA does not suspend or limit a CLIA certificate until after an ALJ hearing decision (as provided in § 493.1844) that upholds suspension or limitation.

(2) *Exceptions.* HCFA may suspend or limit a CLIA certificate before the ALJ hearing in any of the following circumstances:

(i) The laboratory's deficiencies pose immediate jeopardy.

(ii) The laboratory has refused a reasonable request for information or work on materials.

(iii) The laboratory has refused permission for HCFA or a HCFA agent to inspect the laboratory or its operation.

(e) *Procedures for revocation.* (1) HCFA does not revoke any type of CLIA certificate until after an ALJ hearing that upholds revocation.

(2) HCFA may revoke a CLIA certificate after the hearing decision even if it had not previously suspended or limited that certificate.

(f) *Notice to the OIG.* HCFA notifies the OIG of any violations under paragraphs (a)(1), (a)(2), (a)(6), and (b) of this section within 30 days of the determination of the violation.

§ 493.1842 Cancellation of Medicare approval.

(a) *Basis for cancellation.* (1) HCFA always cancels a laboratory's approval to receive Medicare payment for its services if HCFA suspends or revokes the laboratory's CLIA certificate.

(2) HCFA may cancel the laboratory's approval under any of the following circumstances:

(i) The laboratory is out of compliance with a condition level requirement.

(ii) The laboratory fails to submit a plan of correction satisfactory to HCFA.

(iii) The laboratory fails to correct all its deficiencies within the time frames specified in the plan of correction.

(b) *Notice and opportunity to respond.* Before canceling a laboratory's approval to receive Medicare payment for its services, HCFA gives the laboratory—

(1) Written notice of the rationale for, effective date, and effect of, cancellation;

(2) Opportunity to submit written evidence or other information against cancellation of the laboratory's approval.

This sanction may be imposed before the hearing that may be requested by a laboratory, in accordance with the appeals procedures set forth in § 493.1844.

(c) *Effect of cancellation.* Cancellation of Medicare approval terminates any Medicare payment sanctions regardless of the time frames originally specified.

§ 493.1844 Appeals procedures.

(a) *General rules.* (1) The provisions of this section apply to all laboratories and prospective laboratories that are dissatisfied with any initial determination under paragraph (b) of this section.

(2) Hearings are conducted in accordance with procedures set forth in subpart D of part 498 of this chapter, except that the authority to conduct hearings and issue decisions may be exercised by ALJs assigned to, or detailed to, the Departmental Appeals Board.

(3) Any party dissatisfied with a hearing decision is entitled to request review of the decision as specified in subpart E of part 498 of this chapter, except that the authority to review the decision may be exercised by the Departmental Appeals Board.

(4) When more than one of the actions specified in paragraph (b) of this section are carried out concurrently, the laboratory has a right to only one hearing on all matters at issue.

(b) *Actions that are initial determinations.* The following actions are initial determinations and therefore are subject to appeal in accordance with this section:

(1) The suspension, limitation, or revocation of the laboratory's CLIA certificate by HCFA because of noncompliance with CLIA requirements.

(2) The denial of a CLIA certificate.

(3) The imposition of alternative sanctions under this subpart (but not the determination as to which alternative sanction or sanctions to impose).

(4) The denial or cancellation of the laboratory's approval to receive Medicare payment for its services.

(c) *Actions that are not initial determinations.* Actions that are not listed in paragraph (b) of this section are not initial determinations and therefore are not subject to appeal under this section. They include, but are not necessarily limited to, the following:

(1) The finding that a laboratory accredited by a HCFA-approved accreditation organization is no longer deemed to meet the conditions set forth in subparts G through O of this part. However, the suspension, limitation or revocation of a certificate of accreditation is an initial determination and is appealable.

(2) The finding that a laboratory determined to be in compliance with condition-level requirements but has deficiencies that are not at the condition level.

(3) The determination not to reinstate a suspended CLIA certificate because the reason for the suspension has not been removed or there is insufficient assurance that the reason will not recur.

(4) The determination as to which alternative sanction or sanctions to impose, including the amount of a civil money penalty to impose per day or per violation.

(5) The denial of approval for Medicare payment for the services of a laboratory that does not have in effect a valid CLIA certificate.

(6) The determination that a laboratory's deficiencies pose immediate jeopardy.

(7) The amount of the civil money penalty assessed per day or for each violation of Federal requirements.

(d) *Effect of pending appeals*—(1) *Alternative sanctions.* The effective date of an alternative sanction (other than a civil money penalty) is not delayed because the laboratory has appealed and the hearing or the hearing decision is pending.

(2) *Suspension, limitation, or revocation of a laboratory's CLIA certificate*—(i) *General rule.* Except as provided in paragraph (d)(2)(ii) of this section, suspension, limitation, or revocation of a CLIA certificate is not effective until after a hearing decision by an ALJ is issued.

(ii) *Exceptions.* (A) If HCFA determines that conditions at a laboratory pose immediate jeopardy, the effective date of the suspension or limitation of a CLIA certificate is not delayed because the laboratory has appealed and the hearing or the hearing decision is pending.

(B) HCFA may suspend or limit a laboratory's CLIA certificate before an ALJ hearing or hearing decision if the laboratory has refused a reasonable request for information (including but not limited to billing information), or for work on materials, or has refused permission for HCFA or a HCFA agent to inspect the laboratory or its operation.

(3) *Cancellation of Medicare approval.* The effective date of the cancellation of a laboratory's approval to receive Medicare payment for its services is not delayed because the laboratory has appealed and the hearing or hearing decision is pending.

(4) *Effect of ALJ decision.* (i) An ALJ decision is final unless, as provided in paragraph (a)(3) of this section, one of the parties requests review by the Departmental Appeals Board within 60

days, and the Board reviews the case and issues a revised decision.

(ii) If an ALJ decision upholds a suspension imposed because of immediate jeopardy, that suspension becomes a revocation.

(e) *Appeal rights for prospective laboratories*—(1) *Reconsideration.* Any prospective laboratory dissatisfied with a denial of a CLIA certificate, or of approval for Medicare payment for its services, may initiate the appeals process by requesting reconsideration in accordance with §§ 498.22 through 498.25 of this chapter.

(2) *Notice of reopening.* If HCFA reopens an initial or reconsidered determination, HCFA gives the prospective laboratory notice of the revised determination in accordance with § 498.32 of this chapter.

(3) *ALJ hearing.* Any prospective laboratory dissatisfied with a reconsidered determination under paragraph (e)(1) of this section or a revised reconsidered determination under § 498.30 of this chapter is entitled to a hearing before an ALJ, as specified in paragraph (a)(2) of this section.

(4) *Review of ALJ hearing decisions.* Any prospective laboratory that is dissatisfied with an ALJ's hearing decision or dismissal of a request for hearing may file a written request for review by the Departmental Appeals Board as provided in paragraph (a)(3) of this section.

(f) *Appeal rights of laboratories*—(1) *ALJ hearing.* Any laboratory dissatisfied with the suspension, limitation, or revocation of its CLIA certificate, with the imposition of an alternative sanction under this subpart, or with cancellation of the approval to receive Medicare payment for its services, is entitled to a hearing before an ALJ as specified in paragraph (a)(2) of this section and has 60 days from the notice of sanction to request a hearing.

(2) *Review of ALJ hearing decisions.* Any laboratory that is dissatisfied with an ALJ's hearing decision or dismissal of a request for hearing may file a written request for review by the Departmental Appeals Board, as provided in paragraph (a)(3) of this section.

(3) *Judicial review.* Any laboratory dissatisfied with the decision to impose a civil money penalty or to suspend, limit, or revoke its CLIA certificate may, within 60 days after the decision becomes final, file with the U.S. Court of Appeals of the circuit in which the laboratory has its principal place of business, a petition for judicial review.

(g) *Notice of adverse action.* (1) If HCFA suspends, limits, or revokes a laboratory's CLIA certificate or cancels the approval to receive Medicare payment for its services, HCFA gives notice to the laboratory, and may give notice to physicians, providers, suppliers, and other laboratory clients, according to the procedures set forth at § 493.1832. In addition, HCFA notifies the general public each time one of these principal sanctions is imposed.

(2) The notice to the laboratory—

(i) Sets forth the reasons for the adverse action, the effective date and effect of that action, and the appeal rights if any; and

(ii) When the certificate is limited, specifies the specialties or subspecialties of tests that the laboratory is no longer authorized to perform, and that are no longer covered under Medicare.

(3) The notice to other entities includes the same information except the information about the laboratory's appeal rights.

(h) *Effective date of adverse action.* (1) When the laboratory's deficiencies pose immediate jeopardy, the effective date of the adverse action is at least 5 days after the date of the notice.

(2) When HCFA determines that the laboratory's deficiencies do not pose immediate jeopardy, the effective date of the adverse action is at least 15 days after the date of the notice.

§ 493.1846 Civil action.

If HCFA has reason to believe that continuation of the activities of any laboratory, including a State-exempt laboratory, would constitute a significant hazard to the public health, HCFA may bring suit in a U.S. District Court to enjoin continuation of the specific activity that is causing the hazard or to enjoin the continued operation of the laboratory if HCFA deems it necessary. Upon proper showing, the court shall issue a temporary injunction or restraining order without bond against continuation of the activity.

§ 493.1850 Laboratory registry.

(a) Once a year HCFA makes available to physicians and to the general public specific information (including information provided to HCFA by the OIG) that is useful in evaluating the performance of laboratories, including the following:

(1) A list of laboratories that have been convicted, under Federal or State laws relating to fraud and abuse, false billing, or kickbacks.

(2) A list of laboratories that have had their CLIA certificates suspended, limited, or revoked, and the reason for the adverse actions.

(3) A list of persons who have been convicted of violating CLIA requirements, as specified in section 353(1) of the PHS Act, together with the circumstances of each case and the penalties imposed.

(4) A list of laboratories on which alternative sanctions have been imposed, showing—

(i) The effective date of the sanctions;

(ii) The reasons for imposing them;

(iii) Any corrective action taken by the laboratory; and

(iv) If the laboratory has achieved compliance, the verified date of compliance.

(5) A list of laboratories whose accreditation has been withdrawn or revoked and the reasons for the withdrawal or revocation.

(6) All appeals and hearing decisions.

(7) A list of laboratories against which HCFA has brought suit under § 493.1846 and the reasons for those actions.

(8) A list of laboratories that have been excluded from participation in Medicare or Medicaid and the reasons for the exclusion.

(b) The laboratory registry is compiled for the calendar year preceding the date the information is made available and includes appropriate explanatory information to aid in the interpretation of the data. It also contains corrections of any erroneous statements or information that appeared in the previous registry.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Hospital Insurance)

Dated: December 31, 1991.

Gail R. Wilensky,

Administrator, Health Care Financing Administration.

Approved: January 23, 1992.

Louis W. Sullivan,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Specific List for Categorization of Laboratory Test Systems, Assays and Examinations by Complexity

AGENCY: Public Health Service, HHS.

ACTION: Notice with comment period.

SUMMARY: The Clinical Laboratory Improvement Amendments of 1988, Public Law 100–578, requires that the Secretary provide for the categorization of specific laboratory test systems, assays and examinations by level of complexity. 42 CFR 493.17, published elsewhere in this issue of the **Federal Register**, establishes criteria for such categorization.

It is the Department's intention to complete the categorization of all currently available clinical laboratory test systems, assays and examinations prior to the effective date of the amendments to 42 CFR Part 493 (September 1, 1992). This Notice announces the first of a series of lists containing specific clinical laboratory test systems, assays and examinations, categorized by complexity. Additional lists of test systems, assays and examinations will be published periodically. On or before September 1, 1992, a complete list of all laboratory test systems, assays and examinations, categorized by complexity, will be published in the form of a compilation of these Notices. Any clinical laboratory test system, assay or examination that is not on that final list will be considered high complexity, until categorized otherwise, as provided under 42 CFR 493.17. After publication of the compilation, applications will be taken to categorize (or recategorize) other laboratory test systems, assays and examinations following the procedures delineated in 42 CFR 493.17(d). Notices will be published periodically in the **Federal Register** to announce any additional test system, assay or examination that has been categorized (or re-categorized) during the preceding interval.

DATES: *Effective date:* This list is effective September 1, 1992.
Comment date: Written comments on this list of tests will be considered if they are received at the address indicated below, no later than 5 p.m. on March 30, 1992.

ADDRESSES: Comments on the content of this Notice—only—should be addressed to Public Health Service, Attention: CLIA **Federal Register** Notice, 1600 Clifton Rd. NE., (Mail Stop MLR5), Atlanta GA 30333.
Comments pertaining to *the criteria* for test categorization established by 42 CFR part 493 should be adressed to: Health Care Financing Administration, Attention HSQ–176–FC, P.O. Box 26676, Baltimore, MD 21207.
Due to staffing and resource limitations, we cannot accept facsimile (FAX) copies of comments. Nor can we accept comments by telephone.

FOR FURTHER INFORMATION CONTACT: Miley A. Robinson, (404) 639–3153.

SUPPLEMENTARY INFORMATION: As described in 42 CFR 493.17, seven criteria were used to classify laboratory test systems, assays or examinations as moderate or high complexity using a grading scheme for level of complexity that assigned scores of 1, 2 or 3 within each of the seven criteria. Test systems, assays or examinations receiving total scores 12 or under were categorized as moderate complexity, while those receiving total scores of 13 through 21 were categorized as high complexity. As provided under 42 CFR 493.17, the following laboratory test systems, assays and examinations have been categorized as moderate or high complexity as noted.

Dated: January 23, 1992.

James O. Mason,

Assistant Secretary for Health.

Specific List for Categorization of Laboratory Test Systems, Assays and Examinations by Complexity as Provided for in 42 CFR 493.17

Complexity: Moderate

Speciality/Subspeciality: Bacteriology
Analyte: Aerobic Organisms from Cervical/Urethral Specimen
Test Category: Isolation and presumptive Identification of aerobic bacteria from cervical/urethral specimens
Test System, Assay or Examination: All Test Systems, Assays or Examinations
Analyte: Aerobic Organisms from Throat
Test Category: Isolation and confirmatory Identification of aerobic bacteria from throat, urine, or cervical/urethral specimens
Test System, Assay or Examination: All Test Systems, Assays or Examinations
Analyte: All Organisms
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Vitek Systems VITEK
Vitek Systems VITEK AMS ANA Card
Vitek Systems VITEK Anaerobe ID Card
Vitek Systems VITEK/ANI Anaerobes
Vitek Systems VITEK/Bacillus Biochem. card
Vitek Systems VITEK/EPS Enteric path. card
Vitek Systems VITEK/GNI Gram neg ID card
Vitek Systems VITEK/GPI Gram pos ID card
Vitek Systems VITEK/NHI Neisser. & Haemop.
Vitek Systems VITEK/Urine ID 3 card
Test Category: Gram stain
Test System, Assay or Examination: All Test Systems, Assays or Examinations
Test Category: Identification of aerobes from throat, urine, cervical or urethral specimens (e.g. Biochem/Physiol)
Test System, Assay or Examination:
Adams Scientific B. Cat Confirm
Adams Scientific Identicult—AE
Adams Scientific Identicult—BL
Adams Scientific Identicult—Neisseria
Adams Scientific Mug-Indole Disc
Adams Scientific Rapid-Hippurate
Adams Scientific Stat-Urease
Analytab API 20 Streptococcus
Analytab API Laboratories Rapid E
Analytab API Laboratories Rapid NFT
Analytab API Laboratories Rapid Strep
Analytab API StaphTrac
Analytab API Staphase III
Analytab API ZYM Microorganism Differentation
Analytab Quad Ferm +
Baxter Coagulase Plasma
Baxter Haemophilus/Neisseria Identif—Panel
Baxter MicroScan Gram Neg Panels
Baxter MicroScan Gram Pos Panels
Becton Dickinson Cefinase Discs
Becton Dickinson Miniteck
Calbiochem Padac Differentiation Discs
Calbiochem-Behring Anti-Dnase B
Carr Microbiologicals Beta Lactamase Reagent Disc
Carr Microbiologicals CSM Chromogenic B–Lactamase Disc
Carr Microbiologicals Hipp Microtube
Carr Microbiologicals Onpx-Indol Microtube
Carr Microbiologicals PYR Broth
Carr Microbiologicals Pgua-Indol Microtube
Carr Microbiologicals Phos Microtubes
Carr Microbiologicals Pyrr Microtubes
Carr-Scarborough Rapid Glutamic Acid Decarboxy microtube

Diagnostic Products Corp. PathoDx PYR Kit
Difco Differentiation Discs ALA
Difco Differentiation Discs Hippurate
Difco Differentiation Discs Nitrate
Difco Differentiation Discs SPS
Difco Differentiation Discs Spectinomycin
Difco DrySlide Beta-Lactamase
Difco Dryslide Oxidase
Difco Spot Test 10% Na Desoxycholate
E–Y Laboratories Strep-A-Check PYR
E–Y Laboratories Swabzyme-Oxidase
Innovative Diagnostic Systems Beta Discs
Innovative Diagnostic Systems IDS Rapid SS/U System
Innovative Diagnostic Systems IDS Rapid STR system
Innovative Diagnostic Systems Modified IDS Rapid NH System
Innovative Diagnostic Systems Oxichrome Reagent
Innovative Diagnostic Systems Prophyrin Reagent
Innovative Diagnostic Systems Rap NF Plus System
Innovative Diagnostic Systems Rapid NF System
Kev Connecticut Diagnostics Visi-Strep
Meridian Indol Spot Test Kit
Micro Media Systems Bacterial ID Panels/Gram Neg/Gram Pos
Micro Media Systems M. Cat. Butyrate Disc
Micro-Bio-Logics KWIK–LAC
Micro-Bio-Logics Lyfo-KWIK OMI Kit
Micro-Bio-Logics Neisseria-KWIK Plus
Microbiological Specialties Beta-ase Tubes
Microbiological Specialties Enzyme-ase I Tubes
Microbiological Specialties Glactosid-ase Tubes
Microtech Medical Systems Quadra-titer ID
Pasco Labs Gram Neg ID System
Pro-Lab Hippurate Test
Pro-Lab Neisseria/Branhamella Differential Test
Pro-Lab Rosco D'Ala Rapid Test
Pro-Lab Rosco Pyrr
Remel ALA Disc
Remel Beta Lysin Disc
Remel Beta-Lactam Disc
Remel Bile Disc
Remel CEPH Lactam Disc
Remel Catarrhalis Test Strip
Remel Coagulase Plasma
Remel Colistin Disc
Remel Haemophilus ID Test Kit
Remel Hemastaph
Remel Kanamycin Disc
Remel Legionella ID Disc
Remel Microdase
Remel Nitrate Swab-Rapid Test
Remel Novobiocin Disc
Remel PYR Disc
Remel PYR/Esculin Disc
Remel Prophyrin (ALA) Disc
Remel Pyridoxal Disc
Remel SPS Disc
Remel Urea-PDA Discs
Roche Enterotube II
Unipath Oxoid Bile Esculin Discs
Unipath Oxoid ONPG Discs
Unipath Oxoid Oxidase ID Sticks
Unipath Oxoid SPS Discs
Unipath Oxoid V Factor Discs
Unipath Oxoid X & V Factor Discs
Unipath Oxoid X Factor Discs
Vitek Rapid E System

Test Category: Manual procedures with limited steps and limited sample or reagent preparation

Test System, Assay or Examination: Manual antimicrobial susceptibility test (KB Disc Diffus)

Test Category: Manual screening devices for bacteriuria with limited steps and with limited sample or reagent preparation

Test System, Assay or Examination:
Analytab Uriscreen
Miles Diagnostic Labs MicroStix-3 ID
Ventrex Uriscreen

Test Category: Primary culture inoculation

Test System, Assay or Examination: All Test Systems, Assays or Examinations

Test Category: Urine culture and colony count kits

Test System, Assay or Examination:
Culture Kits, Inc. Uri-Kit
Medical Technology Corp. Uricult

Analyte: Campylobacter

Test Category: Manual procedures with limited steps and limited sample or reagent preparation

Test System, Assay or Examination:
Becton Dickinson BBL Campyslide Test
Bio-Medical BIOCARD Campylobacter
Meridian Diagnostics Meritec-Campy (JCL)

Analyte: Chlamydia

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Vitek Systems Vidas Chlamydia (direct antigen)

Test Category: Manual procedures with limited steps and limited sample or reagent preparation

Test System, Assay or Examination:
Abbott TestPack Chlamydia (EIA) (direct antigen)
Analytab IDEIA (EIA) (direct antigen)
Kodak SureCell (EIA) (direct antigen)
Seradyn Vivid Chlamydia (direct antigen)
Unipath Clearview Rapid Assay (direct antigen)

Analyte: Clostridium difficile

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Vitek Systems Vidas C.difficile Toxin A Assay Kit

Test Category: Manual procedures with limited steps and limited sample or reagent preparation

Test System, Assay or Examination:
Becton Dickinson Culturette CDT (direct antigen)
Meridian Diagnostics Meritek (direct antigen)

Analyte: Escherichia coli

Test Category: Manual procedures with limited steps and limited sample or reagent preparation

Test System, Assay or Examination:
Bio-Medical ANI E. Coli 0157 Test (culture confirmation)
Pro-Lab Diagnostics E.Coli 0157 Latex test (culture confirm)
Unipath E. Coli 0157 Latex Kit (direct antigen)

Analyte: Haemophilus influenzae, type a, c-f

Test Category: Manual procedures with limited steps and limited sample or reagent preparation

Test System, Assay or Examination:
Karobio Phadebact Haemophilus (culture confirmation)

Analyte: Haemophilus influenzae, type b

Test Category: Manual procedures with limited steps and limited sample or reagent preparation

Test System, Assay or Examination:
Becton Dickinson Directigen Meningitis (direct antigen)
Becton Dickinson Directigen Meningitis Combo Kit (dir. Ag)
Karobio Phadebact CSF (direct antigen)
Karobio Phadebact Haemophilus (culture confirmation)
Vitek SLIDEX Meningite-Kit 5 (direct antigen)
Wampole Bactigen H. influenzae type b (direct antigen)
Wellcome Wellcogen Bacterial Antigen Kit (direct antigen)

Analyte: Helicobacter pylori

Test Category: Manual procedures with limited steps and limited sample or reagent preparation

Test System, Assay or Examination:
Scimedx Helicobacter pylori Test Kit (direct antigen)

Analyte: Legionella pneumophila

Test Category: Manual procedures with limited steps and limited sample or reagent preparation

Test System, Assay or Examination:

Bio-Medical BIOCARD Legionella
Analyte: Neisseria gonorrhoeae
Test Category: Isolation and presumptive Identification of aerobic bacteria from cervical/urethral specimens
Test System, Assay or Examination:
Culture Kits, Inc. Goni-Kit
Medical Technology Corp. Biocult GC Culture Paddles
Micro-Bio-Logics GONO–KWIK
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Gen-Probe Pace2 (direct antigen)
Karobio Phadebact Monoclonal Gonococcus (culture confirm)
Meridian Diagnostics Meritec-GC (culture confirmation)
New Horizons Gonogen (culture confirmation)
New Horizons Gonogen II (culture confirmation)
Analyte: Neisseria meningitidis (non-specific)
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Becton Dickinson Directigen (direct antigen)
Analyte: Neisseria meningitidis, group A
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Becton Dickinson Directigen Meningitis A&Y (direct antigen)
Karobio Phadebact CSF (direct antigen)
Vitek SLIDEX Meningite-Kit 5 (direct antigen)
Wampole Bactigen N. meningitidis (direct antigen)
Analyte: Neisseria meningitidis, group A and Y
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Becton Dickinson Directigen Meningitis Combo Kit (dir. Ag)
Analyte: Neisseria meningitidis, group B
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Karobio Phadebact CSF (direct antigen)
Wampole Bactigen N. meningitidis (direct antigen)
Analyte: Neisseria meningitidis, group B and E. coli K1
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Becton Dickinson Directigen Meningitis Combo Kit (dir. Ag)
Vitek SLIDEX Meningite-Kit 5 (direct antigen)
Wellcome Wellcogen Bacterial Ag Kit Grp B/E.coli K1(dir Ag)
Analyte: Neisseria meningitidis, group C
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Karobio Phadebact CSF (direct antigen)
Wampole Bactigen N. meningitidis (direct antigen)
Analyte: Neisseria meningitidis, group C and W135
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Becton Dickinson Directigen Meningitis Combo Kit (dir. Ag)
Analyte: Neisseria meningitidis, group G
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Vitek SLIDEX Meningite-Kit 5 (direct antigen)
Analyte: Neisseria meningitidis, group W135
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Karobio Phadebact CSF (direct antigen)
Wampole Bactigen N. meningitidis (direct antigen)
Wellcome Wellcogen Bacterial Ag Kit(Grp A,C,Y,W135)(dir Ag)
Analyte: Neisseria meningitidis, group Y
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Karobio Phadebact CSF (direct antigen)
Wampole Bactigen N. meningitidis (direct antigen)
Analyte: Salmonella
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Ampcor Dipstick Salmonella
Bio-Medical ANI Salmonella Test
Analyte: Staphylococcus
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Adams Scientific SeroStat II Staphylococcus
Advanced Medical Technologies Rapi-Staph
Analytab Staph-Ident
Baxter MicroScan StaphyLatex
Becton Dickinson BBL Staphyloslide
Bio-Medical ANI Staph aureus Test
Carr-Scarborough Accu-Staph
Difco Bacto Staph Latex Test
Immuno-Mycologics LA–Staph
Innovative Diagnostic Systems IDS Staphylochrome
Medical Diagnostics Technologies Staph Latex
NCS Staphslide
Regional Media Lab Hemastaph
Remel Lysostaphin Reagent Set
Vitek RAPIDEC Staph
Wellcome Staphaurex
Analyte: Streptococcus pneumoniae
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Becton Dickinson BBL Pneumoslide (culture confirmation)
Becton Dickinson Directigen Meningitis (direct antigen)
Becton Dickinson Directigen Meningitis Combo Kit (dir. Ag)
Karobio Phadebact CSF (direct antigen)
Karobio Phadebact Pneumococcus (culture confirmation)
Vitek SLIDEX Meningite-Kit 5 (direct antigen)
Wampole Bactigen S. pneumoniae (direct antigen)
Wellcome Wellcogen Bacterial Antigen Kit (direct antigen)
Analyte: Streptococcus, (non-specific)
Test Category: Isolation and confirmatory Identification of aerobic bacteria from throat, urine, or cervical/urethral specimens
Test System, Assay or Examination:
Culture Kits, Inc. Strep-Kit
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Bio-Medical ANI Strep Test
Analyte: Streptococcus, group A
Test Category: Isolation and confirmatory Identification of aerobic bacteria from throat, urine, or cervical/urethral specimens
Test System, Assay or Examination:
Medical Technology Corp. Respiracult—Strep
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Abbott TestPack Strep A (culture confirmation)
Abbott TestPack Strep A (direct antigen)
Adams Scientific SeroStat Streptococcus (culture confirm)
Antibodies Inc. Detect-A-Strep (culture confirmation)
Antibodies Inc. Detect-A-Strep (direct antigen)

Baxter MicroScan Cards (direct antigen)
Baxter MicroScan Microstrep (culture confirmation)
Becton Dickinson BBL Strep Grouping Test (culture conf)
Becton Dickinson Culturette Group A Strep (direct antigen)
Becton Dickinson Directigen 1–2–3 Group A Strep (dir Ag)
Becton Dickinson Directigen Group A Strep (direct antigen)
Becton Dickinson Q Test Strep (direct antigen)
Binax Equate Strep A (culture confirmation)
Binax Equate Strep A (direct antigen)
Clay Adams Q Test StatStrep (direct antigen)
Diagnostic Prod PathoDx Latex Agg. Strep Group (culture con)
Diagnostic Products Corp. PathoDx Strep A (direct antigen)
Hybritech Concise Strep A (direct antigen)
Hybritech Tandem Icon Strep A (direct antigen)
Karobio Phadebact Streptococcus (culture confirmation)
Karobio Phadirect Strep A Test (direct antigen)
Kodak SureCell (culture confirmation)
Kodak SureCell (direct antigen)
Leeco Diagnostics Preview Strep A (direct antigen)
Marion Scientific Group A Strep ID (culture confirmation)
Marion Scientific Group A Strep ID (direct antigen)
Medical Technology Corp. Optitec Strep A (culture confirm)
Medical Technology Corp. Optitec Strep A (direct antigen)
Medical Technology Corp. Respiralex (culture confirmation)
Medical Technology Corp. Respiralex (direct antigen)
Medix Biotech Sure-Strep A (culture confirmation)
Medix Biotech Sure-Strep A (direct antigen)
Meridian Diagnostics Immunocard (direct antigen)
Meridian Diagnostics Meritec-Strep (culture confirmation)
New Horizons Smart (direct antigen)
New Horizons Streptogen (culture confirmation)
Pacific Biotech Cards O.S. Strep A (direct antigen)
Pacific Biotech Cards Strep A (direct antigen)
Unipath Clearview Strep A (direct antigen)
Unipath Oxoid Streptococcal Grouping Kit (culture confirm)
V-Tech Target Strep A (direct antigen)
V-Tech V-Trend Strep A (culture confirmation)
V-Tech V-Trend Strep A (direct antigen)
Ventrex Ventrescreen Strep A (direct antigen)
Wampole Bactigen Group A Strep (direct antigen)
Wellcome Reveal Colour Strep A (culture confirmation)
Wellcome Reveal Colour Strep A (direct antigen)
Wellcome Streptex A (culture confirmation)

Analyte: Streptococcus, group B
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Adams Scientific SeroStat Streptococcus (culture confirm)
Baxter MicroScan Microstrep (culture confirmation)
Becton Dickinson BBL Strep Grouping (culture confirmation)
Becton Dickinson Directigen Group B Strep (direct antigen)
Becton Dickinson Directigen Meningitis Combo Kit (dir. Ag)
Binax Equate Strep B (culture confirmation)
Binax Equate Strep B (direct antigen)
Diagnostic Prod PathoDx Latex Agg. Strep Group (culture con)
Diagnostic Products Corp. PathoDx Strep B (direct antigen)
Hybritech Tandem Icon Strep B (direct antigen)
Karobio Phadebact Streptococcus (culture confirmation)
Marion Scientific Group B Strep ID (culture confirmation)
Marion Scientific Group B Strep ID (direct antigen)
Meridian Diagnostics Meritec-Strep (culture confirmation)
Unipath Oxoid Streptococcal Grouping Kit (culture confirm)
Wampole Bactigen Group B Strep (direct antigen)
Wampole Bactigen Group B Strep-CS (culture confirmation)
Wampole Bactigen Group B Strep-CS (direct antigen)
Wellcome Streptex B (culture confirmation)
Wellcome Wellcogen Bacterial Antigen Kit (direct antigen)

Analyte: Streptococcus, group C
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Adams Scientific SeroStat Streptococcus (culture confirm)
Baxter MicroScan Microstrep (culture confirmation)
Diagnostic Prod PathoDx Latex Agg. Strep Group (culture con)
Karobio Phadebact Streptococcus (culture confirmation)
Meridian Diagnostics Meritec-Strep (culture confirmation)
Unipath Oxoid Streptococcal Grouping Kit (culture confirm)
Wellcome Streptex C (culture confirmation)

Analyte: Streptococcus, group D
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Diagnostic Products Corp. PathoDx Strep D (direct antigen)
Karobio Phadebact Streptococcus (culture confirmation)
Unipath Oxoid Streptococcal Grouping Kit (culture confirm)
Wellcome Streptex D (culture confirmation)

Analyte: Streptococcus, group F
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Adams Scientific SeroStat Streptococcus (culture confirm)
Diagnostic Prod PathoDx Latex Agg. Strep Group (culture con)
Karobio Phadebact Streptococcus (culture confirmation)
Meridian Diagnostics Meritec-Strep (culture confirmation)
Unipath Oxoid Streptococcal Grouping Kit (culture confirm)
Wellcome Streptex F (culture confirmation)

Analyte: Streptococcus, group G
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Adams Scientific SeroStat Streptococcus (culture confirm)
Baxter MicroScan Microstrep (culture confirmation)
Diagnostic Prod PathoDx Latex Agg. Strep Group (culture con)
Karobio Phadebact Streptococcus (culture confirmation)
Meridian Diagnostics Meritec-Strep (culture confirmation)
Unipath Oxoid Streptococcal Grouping Kit (culture confirm)
Wellcome Streptex G (culture confirmation)

Speciality/Subspeciality: General Chemistry
Analyte: 5-Hydroxyindolacetic Acid, Urine (5–HIAA)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx

Analyte: ALT (SGPT)

Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott Spectrum
Abbott Spectrum EPX
Abbott Spectrum Series II
Abbott Spectrum Series II CCX
Abbott VP
Abbott Vision
American Monitor Diagnostics Excel
American Monitor Diagnostics ISP 1000
American Monitor Diagnostics ISP 2000
American Monitor Diagnostics Perspective
Ames Seralyzer III
Baxter Paramax
Baxter Paramax 720 ZX
Beckman Astra Ideal
Beckman Synchron AS–X
Beckman Synchron CX 4
Beckman Synchron CX 5
Beckman Synchron CX 7
Boehringer Mannheim Hitachi 704
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 747
Ciba Corning 550 Express
Ciba Corning 570 Alliance
Ciba Corning 580 Alliance
Coulter Optichem 120
Coulter Optichem 180
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Analyst
Dupont Dimension
Dupont Dimension AR
Electronucleonics Gem-Profiler
Electronucleonics Gemini
Electronucleonics Gemstar
Electronucleonics Gemstar H
Instrumentation Laboratories IL Monarch
Instrumentation Laboratories IL Monarch Plus
Kodak Ektachem 400
Kodak Ektachem 500
Kodak Ektachem 700
Kodak Ektachem 700 XR
Kodak Ektachem DT SC Module
Olympus AU 5000
Olympus Demand
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon AXON
Technicon Assist
Technicon Chem 1
Technicon DAX 24
Technicon DAX 48
Technicon DAX 72
Technicon DAX 96
Technicon RA 1000
Technicon RA 2000
Technicon RA 500
Technicon RA XT
Wako Diagnostics 20R
Wako Diagnostics 30R
Test Category: Whole blood measurements using teststrip meters (excluding glucose monitoring devices cleared by the FDA specifically for home use)
Test System, Assay or Examination:
Boehringer Mannheim Reflotron Plus
Roche Cobas Ready
Analyte: AST (SGOT)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott Spectrum
Abbott Spectrum EPX
Abbott Spectrum Series II
Abbott Spectrum Series II CCX
Abbott VP
Abbott Vision
American Monitor Diagnostics Excel
American Monitor Diagnostics ISP 1000
American Monitor Diagnostics ISP 2000
American Monitor Diagnostics Perspective
Ames Clinistat
Ames Seralyzer
Ames Seralyzer III
Baxter Paramax
Baxter Paramax 720 ZX
Beckman Astra Ideal
Beckman Synchron AS–X
Beckman Synchron CX 4
Beckman Synchron CX 5
Beckman Synchron CX 7
Boehringer Mannheim Hitachi 704
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 747
Ciba Corning 550 Express
Ciba Corning 570 Alliance
Ciba Corning 580 Alliance
Coulter Optichem 120
Coulter Optichem 180
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Analyst
Dupont Dimension
Dupont Dimension AR
Electronucleonics Gem-Profiler
Electronucleonics Gemini
Electronucleonics Gemstar
Electronucleonics Gemstar H
Instrumentation Laboratories IL Monarch
Instrumentation Laboratories IL Monarch Plus
Kodak Ektachem 400
Kodak Ektachem 500
Kodak Ektachem 700
Kodak Ektachem 700 XR
Kodak Ektachem DT SC Module
Olympus AU 5000
Olympus Demand
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon AXON
Technicon Assist
Technicon Chem 1
Technicon DAX 24
Technicon DAX 48
Technicon DAX 72
Technicon DAX 96
Technicon RA 1000
Technicon RA 2000
Technicon RA 500
Technicon RA XT
Wako Diagnostics 20R
Wako Diagnostics 30R
Test Category: Whole blood measurements using teststrip meters (excluding glucose monitoring devices cleared by the FDA specifically for home use)
Test System, Assay or Examination:
Boehringer Mannheim Reflotron Plus
Roche Cobas Ready
Analyte: Acid Phosphatase
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
American Monitor Diagnostics Excel
American Monitor Diagnostics ISP 1000
American Monitor Diagnostics ISP 2000
Baxter Paramax
Baxter Paramax 720 ZX
Beckman Synchron CX 4
Beckman Synchron CX 5
Beckman Synchron CX 7
Boehringer Mannheim Hitachi 704
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 747
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Dupont Dimension AR
Electronucleonics Gem-Profiler
Electronucleonics Gemini
Electronucleonics Gemstar
Electronucleonics Gemstar H
Instrumentation Laboratories IL Monarch
Instrumentation Laboratories IL Monarch Plus
Kodak Ektachem 400
Kodak Ektachem 500

Kodak Ektachem 700 XR
Olympus AU 5000
Olympus Demand
Technicon Assist
Technicon Chem 1
Technicon RA 1000
Technicon RA 500

Analyte: Albumin
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott Spectrum
Abbott Spectrum EPX
Abbott Spectrum Series II
Abbott Spectrum Series II CCX
Abbott VP
Abbott Vision
American Monitor Diagnostics Excel
American Monitor Diagnostics ISP 1000
American Monitor Diagnostics ISP 2000
American Monitor Diagnostics Perspective
Baxter Paramax
Baxter Paramax 720 ZX
Beckman Array 360
Beckman Astra Ideal
Beckman Synchron AS–X
Beckman Synchron CX 4
Beckman Synchron CX 5
Beckman Synchron CX 7
Boehringer Mannheim Hitachi 704
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 747
Ciba Corning 550 Express
Ciba Corning 570 Alliance
Ciba Corning 580 Alliance
Coulter Optichem 120
Coulter Optichem 180
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Dupont Dimension AR
Electronucleonics Gem-Profiler
Electronucleonics Gemini
Electronucleonics Gemstar
Electronucleonics Gemstar II
Instrumentation Laboratories IL Monarch
Instrumentation Laboratories IL Monarch Plus
Kodak Ektachem 400
Kodak Ektachem 500
Kodak Ektachem 700
Kodak Ektachem 700 XR
Olympus AU 5000
Olympus Demand
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon AXON
Technicon Assist
Technicon Chem 1
Technicon DAX 24
Technicon DAX 48
Technicon DAX 72
Technicon DAX 96
Technicon RA 1000
Technicon RA 2000
Technicon RA 500
Technicon RA XT
Wako Diagnostics 20R
Wako Diagnostics 30R

Analyte: Aldolase
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Boehringer Mannheim Hitachi 717

Analyte: Alkaline Phosphatase (ALP)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott Spectrum
Abbott Spectrum EPX
Abbott Spectrum Series II
Abbott Spectrum Series II CCX
Abbott VP
Abbott Vision
American Monitor Diagnostics Excel
American Monitor Diagnostics ISP 1000
American Monitor Diagnostics ISP 2000
American Monitor Diagnostics Perspective
Baxter Paramax
Baxter Paramax 720 ZX
Beckman Astra Ideal
Beckman Synchron AS–X
Beckman Synchron CX 4
Beckman Synchron CX 5
Beckman Synchron CX 7
Boehringer Mannheim Hitachi 704
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 747
Ciba Corning 550 Express
Ciba Corning 570 Alliance
Ciba Corning 580 Alliance
Coulter Optichem 120
Coulter Optichem 180
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Analyst
Dupont Dimension
Dupont Dimension AR
Electronucleonics Gem-Profiler
Electronucleonics Gemini
Electronucleonics Gemstar
Electronucleonics Gemstar II
Instrumentation Laboratories IL Monarch
Instrumentation Laboratories IL Monarch Plus
Kodak Ektachem 400
Kodak Ektachem 500
Kodak Ektachem 700
Kodak Ektachem 700 XR
Kodak Ektachem DT SC Module
Olympus AU 5000
Olympus Demand
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon AXON
Technicon Assist
Technicon Chem 1
Technicon DAX 24
Technicon DAX 48
Technicon DAX 72
Technicon DAX 96
Technicon RA 1000
Technicon RA 2000
Technicon RA 500
Technicon RA XT
Wako Diagnostics 20R
Wako Diagnostics 30R

Analyte: Alpha-Hydroxybutyrate Dehydrogenase (HBDH)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Boehringer Mannheim Hitachi 705
Ciba Corning 550 Express
Dupont ACA IV
Dupont ACA V

Analyte: Ammonia
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Baxter Paramax
Baxter Paramax 720 ZX
Boehringer Mannheim Hitachi 717
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Instrumentation Laboratories IL Monarch Plus
Kodak Ektachem 500
Kodak Ektachem 700 XR
Kodak Ektachem DT 60

Analyte: Amylase
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott Spectrum EPX
Abbott Spectrum Series II
Abbott Spectrum Series II CCX
Abbott TDX
Abbott TDX FLx
Abbott VP
Abbott Vision
American Monitor Diagnostics Excel

American Monitor Diagnostics ISP 1000
American Monitor Diagnostics ISP 2000
American Monitor Diagnostics Perspective
Baxter Paramax
Baxter Paramax 720 ZX
Beckman Astra 8
Beckman Astra Ideal
Beckman Synchron AS–X
Beckman Synchron CX 4
Beckman Synchron CX 5
Beckman Synchron CX 7
Boehringer Mannheim Hitachi 704
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 747
Ciba Corning 550 Express
Ciba Corning 570 Alliance
Ciba Corning 580 Alliance
Coulter Optichem 120
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Analyst
Dupont Dimension
Dupont Dimension AR
Electronucleonics Gem-Profiler
Electronucleonics Gemini
Electronucleonics Gemstar
Electronucleonics Gemstar II
Instrumentation Laboratories IL Monarch
Instrumentation Laboratories IL Monarch Plus
Kodak Ektachem 400
Kodak Ektachem 500
Kodak Ektachem 700
Kodak Ektachem 700 XR
Kodak Ektachem DT 60
Olympus AU 5000
Olympus Demand
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon AXON
Technicon Assist
Technicon Chem 1
Technicon DAX 24
Technicon DAX 48
Technicon DAX 72
Technicon DAX 96
Technicon RA 1000
Technicon RA 2000
Technicon RA 500
Technicon RA XT
Wako Diagnostics 20R
Wako Diagnostics 30R

Test Category: Whole blood measurements using teststrip meters (excluding glucose monitoring devices cleared by the FDA specifically for home use)

Test System, Assay or Examination:

Boehringer Mannheim Reflotron Plus

Analyte: Bilirubin, Direct

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:

Abbott Spectrum
Abbott Spectrum EPX
Abbott Spectrum Series II
Abbott Spectrum Series II CCX
Abbott VP
American Monitor Diagnostics Excel
American Monitor Diagnostics ISP 1000
American Monitor Diagnostics ISP 2000
American Monitor Diagnostics Perspective
Baxter Paramax
Baxter Paramax 720 ZX
Beckman Astra Ideal
Beckman Synchron AS–X
Beckman Synchron CX 4
Beckman Synchron CX 5
Beckman Synchron CX 7
Boehringer Mannheim Hitachi 704
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 747
Ciba Corning 550 Express
Ciba Corning 570 Alliance
Ciba Corning 580 Alliance
Coulter Optichem 120
Coulter Optichem 180
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Dupont Dimension AR
Electronucleonics Gem-Profiler
Electronucleonics Gemini
Electronucleonics Gemstar
Electronucleonics Gemstar II
Instrumentation Laboratories IL Monarch
Instrumentation Laboratories IL Monarch Plus
Kodak Ektachem 400
Kodak Ektachem 500
Kodak Ektachem 700
Kodak Ektachem 700 XR
Olympus AU 5000
Olympus Demand
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon AXON
Technicon Assist
Technicon Chem 1
Technicon DAX 24
Technicon DAX 48
Technicon DAX 72
Technicon DAX 96
Technicon RA 1000
Technicon RA 2000
Technicon RA 500
Technicon RA XT
Wako Diagnostics 20R
Wako Diagnostics 30R

Analyte: Bilirubin, Neonatal

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:

Advanced Instruments Bilirubin STAT Analyzer
Dupont ACA
Dupont ACA IV
Dupont ACA V

Analyte: Bilirubin, Total

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:

Abbott Spectrum
Abbott Spectrum EPX
Abbott Spectrum Series II
Abbott Spectrum Series II CCX
Abbott VP
Abbott Vision
American Monitor Diagnostics Excel
American Monitor Diagnostics ISP 1000
American Monitor Diagnostics ISP 2000
American Monitor Diagnostics Perspective
Ames Clinistat
Ames Seralyzer
Ames Seralyzer III
Baxter Paramax
Baxter Paramax 720 ZX
Beckman Astra Ideal
Beckman Synchron AS–X
Beckman Synchron CX 4
Beckman Synchron CX 5
Beckman Synchron CX 7
Boehringer Mannheim Hitachi 704
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 747
Ciba Corning 550 Express
Ciba Corning 570 Alliance
Ciba Corning 580 Alliance
Coulter Optichem 120
Coulter Optichem 180
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Analyst
Dupont Dimension
Dupont Dimension AR
Electronucleonics Gem-Profiler
Electronucleonics Gemini
Electronucleonics Gemstar
Electronucleonics Gemstar II
Instrumentation Laboratories IL Monarch
Instrumentation Laboratories IL Monarch Plus

Kodak Ektachem 400
Kodak Ektachem 500
Kodak Ektachem 700
Kodak Ektachem 700 XR
Kodak Ektachem DT 60
Olympus AU 5000
Olympus Demand
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon AXON
Technicon Assist
Technicon Chem 1
Technicon DAX 24
Technicon DAX 48
Technicon DAX 72
Technicon DAX 96
Technicon RA 1000
Technicon RA 2000
Technicon RA 500
Technicon RA XT
Wako Diagnostics 20R
Wako Diagnostics 30R

Test Category: Whole blood measurements using teststrip meters (excluding glucose monitoring devices cleared by the FDA specifically for home use)

Test System, Assay or Examination:
Boehringer Mannheim Reflotron Plus
Roche Cobas Ready

Analyte: Blood Gases

Test Category: Automated blood gas analyses that do not require operator intervention during the analytic process, such as instruments that have an automated process for calibration, sample intake and flushing of sample lines

Test System, Assay or Examination:
AVL 940
AVL 945
AVL 990
AVL 995
AVL 995 Hb
Ciba Corning 278
Ciba Corning 280
Ciba Corning 288
Instrumentation Laboratories BG Electrolytes
Instrumentation Laboratories IL 1301
Instrumentation Laboratories IL 1302
Instrumentation Laboratories IL 1303
Instrumentation Laboratories IL 1304
Instrumentation Laboratories IL 1306
Instrumentation Laboratories IL 1312
Instrumentation Laboratories IL 813
Mallinckrodt Gem 6 Plus
Mallinckrodt Gem Premier
Nova Stat Profile
Radiometer ABL 2
Radiometer ABL 3
Radiometer ABL 30
Radiometer ABL 300
Radiometer ABL 330
Radiometer ABL 4

Analyte: CK MB

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Abbott IMX
Baxter Paramax
Baxter Paramax 720 ZX
Baxter Stratus
Baxter Stratus II
Beckman Synchron CX 7
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 747
Ciba Corning ACS 180
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Instrumentation Laboratories IL Monarch Plus
Kodak Ektachem 500
Kodak Ektachem 700 XR
Kodak Ektachem DT SC Module

Test Category: Manual procedures with limited steps and limited sample or reagent preparation

Test System, Assay or Examination:
Hybritech ICON QSR CKMB

Analyte: CO2

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
AVL 986–S
Abbott VP
American Monitor Diagnostics Excel
American Monitor Diagnostics ISP 1000
American Monitor Diagnostics ISP 2000
American Monitor Diagnostics Perspective
Baxter Paramax
Baxter Paramax 720 ZX
Beckman Astra 4
Beckman Astra 8
Beckman Astra Ideal
Beckman E2A
Beckman E4A
Beckman Synchron AS–X
Beckman Synchron CX 3
Beckman Synchron CX 4
Beckman Synchron CX 5
Beckman Synchron CX 7
Beckman Synchron EL–ISE
Boehringer Mannheim Hitachi 704
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 747
Ciba Corning 550 Express
Ciba Corning 570 Alliance
Ciba Corning 580 Alliance
Ciba Corning 664 FAST 4
Coulter Optichem 120
Coulter Optichem 180
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Dupont Dimension AR
Electronucleonics Gem-Profiler
Electronucleonics Gemini
Electronucleonics Gemstar
Electronucleonics Gemstar II
Instrumentation Laboratories IL Monarch
Instrumentation Laboratories IL Monarch Plus
Instrumentation Laboratories Phoenix
Kodak Ektachem 400
Kodak Ektachem 500
Kodak Ektachem 700
Kodak Ektachem 700 XR
Kodak Ektachem DTE Module
Olympus AU 5000
Olympus Demand
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon AXON
Technicon Assist
Technicon Chem 1
Technicon DAX 24
Technicon DAX 48
Technicon DAX 72
Technicon DAX 96
Technicon RA 1000
Technicon RA 2000
Technicon RA 500
Technicon RA XT
Wako Diagnostics 20R
Wako Diagnostics 30R

Analyte: Calcium, ionized

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
AVL 984–S
AVL 987–S
Beckman LABLYTE 820
Beckman Synchron EL–ISE
Ciba Corning 634
Coulter FLEXLYTE 3
Coulter FLEXLYTE 6
Instrumentation Laboratories BGElectrolytes
Mallinckrodt Gem 6 Plus
Mallinckrodt Gem Premier
Radiometer ICA 1

Analyte: Calcium, total

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Abbott Spectrum
Abbott Spectrum EPX
Abbott Spectrum Series II
Abbott Spectrum Series II CCX
Abbott VP
Abbott Vision
American Monitor Diagnostics Excel
American Monitor Diagnostics ISP 1000

American Monitor Diagnostics ISP 2000
American Monitor Diagnostics Perspective
Baxter Paramax
Baxter Paramax 720 ZX
Beckman Astra 8
Beckman Astra Ideal
Beckman Synchron CX 3
Beckman Synchron CX 4
Beckman Synchron CX 5
Beckman Synchron CX 7
Boehringer Mannheim Hitachi 704
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 747
Ciba Corning 550 Express
Ciba Corning 570 Alliance
Ciba Corning 580 Alliance
Coulter Optichem 120
Coulter Optichem 180
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Analyst
Dupont Dimension
Dupont Dimension AR
Electronucleonics Gem-Profiler
Electronucleonics Gemini
Electronucleonics Gemstar
Electronucleonics Gemstar II
Instrumentation Laboratories IL Monarch
Instrumentation Laboratories IL Monarch Plus
Instrumentation Laboratories Phoenix
Kodak Ektachem 400
Kodak Ektachem 500
Kodak Ektachem 700
Kodak Ektachem 700 XR
Kodak Ektachem DT SC Module
Olympus AU 5000
Olympus Demand
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon AXON
Technicon Assist
Technicon Chem 1
Technicon DAX 24
Technicon DAX 48
Technicon DAX 72
Technicon DAX 96
Technicon RA 1000
Technicon RA 2000
Technicon RA 500
Technicon RA XT
Wako Diagnostics 20R
Wako Diagnostics 30R

Analyte: Carboxyhemoglobin
Test Category: Automated blood gas analyses that do not require operator intervention during the analytic process, such as instruments that have an automated process for calibration, sample intake and flushing of sample lines
Test System, Assay or Examination:
AVL 912
AVL 995 Hb

Analyte: Cerebrospinal Fluid Protein
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Instrumentation Laboratories IL Monarch Plus
Kodak Ektachem 400
Kodak Ektachem 700 XR

Analyte: Chloride
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
AVL 983–S
AVL 986–S
Abbott Spectrum
Abbott Spectrum EPX
Abbott Spectrum Series II
Abbott Spectrum Series II CCX
Abbott VP
American Monitor Diagnostics Excel
American Monitor Diagnostics ISP 1000
American Monitor Diagnostics ISP 2000
American Monitor Diagnostics Perspective
Baxter Paramax
Baxter Paramax 720 ZX
Beckman Astra 8
Beckman Astra Ideal
Beckman E2A
Beckman E4A
Beckman LABLYTE 810
Beckman Synchron AS–X
Beckman Synchron CX 3
Beckman Synchron CX 4
Beckman Synchron CX 5
Beckman Synchron CX 7
Beckman Synchron EL–ISE
Boehringer Mannheim Hitachi 704
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 747
Ciba Corning 550 Express
Ciba Corning 570 Alliance
Ciba Corning 580 Alliance
Ciba Corning 644
Ciba Corning 664 FAST 4
Coulter FLEXLYTE 3
Coulter FLEXLYTE 6
Coulter Optichem 120
Coulter Optichem 180
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Dupont Dimension AR
Electronucleonics Gem-Profiler
Electronucleonics Gemini
Electronucleonics Gemstar
Electronucleonics Gemstar II
Instrumentation Laboratories IL Monarch
Instrumentation Laboratories IL Monarch Plus
Instrumentation Laboratories Phoenix
Kodak Ektachem 400
Kodak Ektachem 500
Kodak Ektachem 700
Kodak Ektachem 700 XR
Kodak Ektachem DTE Module
Medica Easylite Plus Ion Selective Analyzer
Olympus AU 5000
Olympus Demand
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon AXON
Technicon Chem 1
Technicon DAX 24
Technicon DAX 48
Technicon DAX 72
Technicon DAX 96
Technicon RA 1000
Technicon RA 2000
Technicon RA 500
Technicon RA XT
Wako Diagnostics 20R
Wako Diagnostics 30R

Analyte: Cholesterol
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott Spectrum
Abbott Spectrum EPX
Abbott Spectrum Series II
Abbott Spectrum Series II CCX
Abbott TDX
Abbott TDX FLx
Abbott VP
Abbott Vision
American Monitor Diagnostics Excel
American Monitor Diagnostics ISP 1000
American Monitor Diagnostics ISP 2000
American Monitor Diagnostics Perspective
Ames Clinistat
Ames Seralyzer
Ames Seralyzer III
Baxter Paramax
Baxter Paramax 720 ZX
Beckman Astra Ideal
Beckman Synchron AS–X
Beckman Synchron CX 4
Beckman Synchron CX 5
Beckman Synchron CX 7
Boehringer Mannheim Hitachi 704
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717

Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 747
Ciba Corning 550 Express
Ciba Corning 570 Alliance
Ciba Corning 580 Alliance
Coulter Optichem 120
Coulter Optichem 180
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Analyst
Dupont Dimension
Dupont Dimension AR
Electronucleonics Gem-Profiler
Electronucleonics Gemini
Electronucleonics Gemstar
Electronucleonics Gemstar II
Instrumentation Laboratories IL Monarch
Instrumentation Laboratories IL Monarch Plus
Kodak Ektachem 400
Kodak Ektachem 500
Kodak Ektachem 700
Kodak Ektachem 700 XR
Kodak Ektachem DT 60
Olympus AU 5000
Olympus Demand
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon AXON
Technicon Assist
Technicon Chem 1
Technicon DAX 24
Technicon DAX 48
Technicon DAX 72
Technicon DAX 96
Technicon RA 1000
Technicon RA 2000
Technicon RA 500
Technicon RA XT
Wako Diagnostics 20R
Wako Diagnostics 30R

Test Category: Whole blood measurements using teststrip meters (excluding glucose monitoring devices cleared by the FDA specifically for home use)

Test System, Assay or Examination:
Boehringer Mannheim Reflotron
Boehringer Mannheim Reflotron Plus
Roche Cobas Ready

Analyte: Cholinesterase

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
American Monitor Diagnostics Excel
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 747
Ciba Corning 550 Express
Instrumentation Laboratories IL Monarch Plus

Analyte: Cortisol

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Baxter Stratus
Baxter Stratus II
Boehringer Mannheim ES 300

Analyte: Cortisol, Urine

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Abbott TDX FLx

Analyte: Creatine Kinase (CK)

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Abbott Spectrum
Abbott Spectrum EPX
Abbott Spectrum Series II
Abbott Spectrum Series II CCX
Abbott VP
Abbott Vision
American Monitor Diagnostics Excel
American Monitor Diagnostics ISP 1000
American Monitor Diagnostics ISP 2000
American Monitor Diagnostics Perspective
Ames Clinistat
Ames Seralyzer III
Baxter Paramax
Baxter Paramax 720 ZX
Beckman Astra Ideal
Beckman Synchron AS–X
Beckman Synchron CX 4
Beckman Synchron CX 5
Beckman Synchron CX 7
Boehringer Mannheim Hitachi 704
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 747
Ciba Corning 550 Express
Ciba Corning 570 Alliance
Ciba Corning 580 Alliance
Coulter Optichem 120
Coulter Optichem 180
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Dupont Dimension AR
Electronucleonics Gem-Profiler
Electronucleonics Gemini
Electronucleonics Gemstar
Electronucleonics Gemstar II
Instrumentation Laboratories IL Monarch
Instrumentation Laboratories IL Monarch Plus
Kodak Ektachem 400
Kodak Ektachem 500
Kodak Ektachem 700
Kodak Ektachem 700 XR
Kodak Ektachem DT SC Module
Olympus AU 5000
Olympus Demand
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon AXON
Technicon Assist
Technicon Chem 1
Technicon DAX 24
Technicon DAX 48
Technicon DAX 72
Technicon DAX 96
Technicon RA 1000
Technicon RA 2000
Technicon RA 500
Technicon RA XT
Wako Diagnostics 20R
Wako Diagnostics 30R

Test Category: Whole blood measurements using teststrip meters (excluding glucose monitoring devices cleared by the FDA specifically for home use)

Test System, Assay or Examination:
Boehringer Mannheim Reflotron Plus
Roche Cobas Ready

Analyte: Creatinine

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Abbott Spectrum
Abbott Spectrum EPX
Abbott Spectrum Series II
Abbott Spectrum Series II CCX
Abbott TDX
Abbott TDX FLx
Abbott VP
Abbott Vision
American Monitor Diagnostics Excel
American Monitor Diagnostics ISP 1000
American Monitor Diagnostics ISP 2000
American Monitor Diagnostics Perspective
Ames Clinistat
Ames Seralyzer
Ames Seralyzer III
Baxter Paramax
Baxter Paramax 720 ZX
Beckman Astra 4
Beckman Astra 8
Beckman Astra Ideal
Beckman Creatinine Analyzer (Original Model)
Beckman Creatinine Analyzer 2
Beckman Synchron AS–X
Beckman Synchron CX 3
Beckman Synchron CX 4
Beckman Synchron CX 5

Beckman Synchron CX 7
Boehringer Mannheim Hitachi 704
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 747
Ciba Corning 550 Express
Ciba Corning 570 Alliance
Ciba Corning 580 Alliance
Coulter Optichem 120
Coulter Optichem 180
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Analyst
Dupont Dimension
Dupont Dimension AR
Electronucleonics Gem-Profiler
Electronucleonics Gemini
Electronucleonics Gemstar
Electronucleonics Gemstar II
Instrumentation Laboratories IL Monarch
Instrumentation Laboratories IL Monarch Plus
Instrumentation Laboratories Phoenix
Kodak Ektachem 400
Kodak Ektachem 500
Kodak Ektachem 700
Kodak Ektachem 700 XR
Kodak Ektachem DT 60
Olympus AU 5000
Olympus Demand
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon AXON
Technicon Assist
Technicon Chem 1
Technicon DAX 24
Technicon DAX 48
Technicon DAX 72
Technicon DAX 96
Technicon RA 1000
Technicon RA 2000
Technicon RA 500
Technicon RA XT
Wako Diagnostics 20R
Wako Diagnostics 30R

Test Category: Whole blood measurements using teststrip meters (excluding glucose monitoring devices cleared by the FDA specifically for home use)

Test System, Assay or Examination:
Boehringer Mannheim Reflotron
Boehringer Mannheim Reflotron Plus
Roche Cobas Ready

Analyte: Estradiol

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Abbott IMX

Analyte: Estriol—Total

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Abbott TDX
Abbott TDX
Abbott TDX FLx

Analyte: Estriol—Unconjugated

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx

Analyte: Ferritin

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Abbott IMX
Baxter Stratus
Baxter Stratus II
Becton-Dickinson Affinity
Boehringer Mannheim ES 300
Ciba Corning ACS 180

Analyte: Folate (Folic acid)

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Abbott IMX
Ciba Corning ACS 180

Analyte: Follicle Stimulating Hormone (FSH)

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Abbott IMX
Baxter Stratus
Baxter Stratus II
Becton-Dickinson Affinity
Boehringer Mannheim ES 300
Ciba Corning ACS 180
PB Diagnostics OPUS

Analyte: Gamma Glutamyl Transferase (GGT)

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Abbott Spectrum
Abbott Spectrum EPX
Abbott Spectrum Series II
Abbott Spectrum Series II CCX
Abbott VP
Abbott Vision
American Monitor Diagnostics Excel
American Monitor Diagnostics ISP 1000
American Monitor Diagnostics ISP 2000
American Monitor Diagnostics Perspective
Baxter Paramax
Baxter Paramax 720 ZX
Beckman Astra Ideal
Beckman Synchron AS–X
Beckman Synchron CX 4
Beckman Synchron CX 5
Beckman Synchron CX 7
Boehringer Mannheim Hitachi 704
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 747
Ciba Corning 550 Express
Ciba Corning 570 Alliance
Ciba Corning 580 Alliance
Coulter Optichem 120
Coulter Optichem 180
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Analyst
Dupont Dimension
Dupont Dimension AR
Electronucleonics Gem-Profiler
Electronucleonics Gemini
Electronucleonics Gemstar
Electronucleonics Gemstar II
Instrumentation Laboratories IL Monarch
Instrumentation Laboratories IL Monarch Plus
Kodak Ektachem 400
Kodak Ektachem 500
Kodak Ektachem 700
Kodak Ektachem 700 XR
Kodak Ektachem DT SC Module
Olympus AU 5000
Olympus Demand
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon AXON
Technicon Assist
Technicon Chem 1
Technicon DAX 24
Technicon DAX 48
Technicon DAX 72
Technicon DAX 96
Technicon RA 1000
Technicon RA 2000
Technicon RA 500
Technicon RA XT
Wako Diagnostics 20R
Wako Diagnostics 30R

Test Category: Whole blood measurements using teststrip meters (excluding glucose monitoring devices cleared by the FDA specifically for home use)

Test System, Assay or Examination:
Boehringer Mannheim Reflotron Plus

Analyte: Glucose

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:

Abbott Spectrum
Abbott Spectrum EPX
Abbott TDX
Abbott TDX FLx
Abbott VP
Abbott Vision
American Monitor Diagnostics Excel
American Monitor Diagnostics ISP 1000
American Monitor Diagnostics ISP 2000
American Monitor Diagnostics Perspective
Ames Clinistat
Ames Seralyzer
Ames Seralyzer III
Baxter Paramax
Baxter Paramax 720 ZX
Beckman Astra 4
Beckman Astra 8
Beckman Astra Ideal
Beckman Glucose Analyzer (Original Model)
Beckman Glucose Analyzer 2
Beckman Synchron AS–X
Beckman Synchron CX 3
Beckman Synchron CX 4
Beckman Synchron CX 5
Boehringer Mannheim Hitachi 704
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 747
Ciba Corning 550 Express
Ciba Corning 570 Alliance
Ciba Corning 580 Alliance
Coulter Optichem 120
Coulter Optichem 180
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Analyst
Dupont Dimension
Electronucleonics Gem-Profiler
Electronucleonics Gemini
Electronucleonics Gemstar
Electronucleonics Gemstar II
Instrumentation Laboratories IL Monarch
Instrumentation Laboratories IL Monarch Plus
Instrumentation Laboratories Phoenix
Kodak Ektachem 500
Kodak Ektachem 700
Kodak Ektachem 700 XR
Kodak Ektachem DT 60
Olympus AU 5000
Olympus Demand
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon AXON
Technicon Assist
Technicon Chem 1
Technicon DAX 24
Technicon DAX 48
Technicon DAX 72
Technicon DAX 96
Technicon RA 1000
Technicon RA 2000
Technicon RA 500
Technicon RA XT
Wako Diagnostics 20R
Wako Diagnostics 30R
Yellow Springs YSI Model 1500
Yellow Springs YSI Model 2300

Test Category: Whole blood measurements using teststrip meters (excluding glucose monitoring devices cleared by the FDA specifically for home use)

Test System, Assay or Examination:
Boehringer Mannheim Reflotron
Boehringer Mannheim Reflotron Plus
Roche Cobas Ready

Analyte: HCG, Serum, Qualitative

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Becton Dickinson Affinity

Test Category: Manual procedures with limited steps and limited sample or reagent preparation

Test System, Assay or Examination:
Abbott TestPack HCG-combo
Ampcor Quik-Dot Pregnancy Dipstick
Biomerica Nimbus
Hybritech Tandem ICON II
Sequoia Turner Clearview HCG

Analyte: HCG, Serum, Quantitative

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Abbott IMX
Baxter Stratus
Baxter Stratus II
Boehringer Mannheim ES 300
Ciba Corning ACS 180
PB Diagnostics OPUS

Analyte: HCG, Urine

Test Category: Manual procedures with limited steps and limited sample or reagent preparation

Test System, Assay or Examination:
Abbott TestPack HCG-combo
Abbott TestPack Plus
Ampcor Quik-Dot Pregnancy Dipstick
Biomerica Nimbus
Hybritech Concise HCG
Hybritech Tandem ICON II
Roche Pregnosis

Analyte: HDL Cholesterol

Test Category: Whole blood measurements using teststrip meters (excluding glucose monitoring devices cleared by the FDA specifically for home use)

Test System, Assay or Examination:
Boehringer Mannheim Reflotron Plus

Analyte: Insulin

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Abbott IMX
Boehringer Mannheim ES 300

Analyte: Iron

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Abbott VP
American Monitor Diagnostics Excel
American Monitor Diagnostics ISP 1000
American Monitor Diagnostics ISP 2000
American Monitor Diagnostics Perspective
Baxter Paramax
Baxter Paramax 720 ZX
Beckman Synchron CX 4
Beckman Synchron CX 5
Beckman Synchron CX 7
Boehringer Mannheim Hitachi 704
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 747
Ciba Corning 550 Express
Coulter Optichem 120
Coulter Optichem 180
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Dupont Dimension AR
Electronucleonics Gem-Profiler
Electronucleonics Gemini
Electronucleonics Gemstar
Electronucleonics Gemstar II
Instrumentation Laboratories IL Monarch
Instrumentation Laboratories IL Monarch Plus
Kodak Ektachem 400
Kodak Ektachem 500
Kodak Ektachem 700
Kodak Ektachem 700 XR
Olympus AU 5000
Olympus Demand
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon AXON
Technicon Assist
Technicon Chem 1
Technicon DAX 24
Technicon DAX 48
Technicon DAX 72
Technicon DAX 96
Technicon RA 1000
Technicon RA 2000
Technicon RA 500

Technicon RA XT
Wako Diagnostics 20R
Wako Diagnostics 30R
Analyte: Lactate Dehydrogenase (LDH)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott Spectrum
Abbott Spectrum EPX
Abbott Spectrum Series II
Abbott Spectrum Series II CCX
Abbott TDX
Abbott TDX FLx
Abbott VP
Abbott Vision
American Monitor Diagnostics Excel
American Monitor Diagnostics ISP 1000
American Monitor Diagnostics ISP 2000
American Monitor Diagnostics Perspective
Ames Clinistat
Ames Seralyzer
Ames Seralyzer III
Baxter Paramax
Baxter Paramax 720 ZX
Beckman Astra Ideal
Beckman Synchron AS–X
Beckman Synchron CX 4
Beckman Synchron CX 5
Beckman Synchron CX 7
Boehringer Mannheim Hitachi 704
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 747
Ciba Corning 550 Express
Ciba Corning 570 Alliance
Ciba Corning 580 Alliance
Coulter Optichem 120
Coulter Optichem 180
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Dupont Dimension AR
Electronucleonics Gem-Profiler
Electronucleonics Gemini
Electronucleonics Gemstar
Electronucleonics Gemstar II
Instrumentation Laboratories IL Monarch
Instrumentation Laboratories IL Monarch Plus
Kodak Ektachem 400
Kodak Ektachem 500
Kodak Ektachem 700
Kodak Ektachem 700 XR
Kodak Ektachem DT SC Module
Olympus AU 5000
Olympus Demand
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon AXON
Technicon Assist
Technicon Chem 1
Technicon DAX 24
Technicon DAX 48
Technicon DAX 72
Technicon DAX 96
Technicon RA 1000
Technicon RA 2000
Technicon RA 500
Technicon RA XT
Wako Diagnostics 20R
Wako Diagnostics 30R
Analyte: Lactate Dehydrogenase Heart Fraction (LDH–1)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Boehringer Mannheim Hitachi 717
Analyte: Lactate Dehydrogenase Liver Fraction (LLDH)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Dupont ACA IV
Dupont ACA V
Analyte: Lactic Acid (Lactate)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Baxter Paramax
Baxter Paramax 720 ZX
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Kodak Ektachem 700 XR
Yellow Springs YSI Model 1500 Sport
Yellow Springs YSI Model 2300
Yellow Springs YSI Model 2372
Analyte: Leucine Aminopeptidase (LAP)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Boehringer Mannheim Hitachi 705
Instrumentation Laboratories IL Monarch Plus
Analyte: Lipase
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Instrumentation Laboratories IL Monarch Plus
Kodak Ektachem 500
Kodak Ektachem 500
Kodak Ektachem 700 XR
Analyte: Lithium
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
AVL 985–S
AVL 985–S1
Abbott TDX FLx
Amdev ISE Analyzer
Baxter Paramax
Baxter Paramax 720 ZX
Beckman LABLYTE 830
Beckman LABLYTE 830
Beckman Synchron EL–ISE
Ciba Corning 654
Coulter FLEXLYTE 3
Coulter FLEXLYTE 6
Dupont Na, K, Li Analyzer
Analyte: Luteinizing Hormone (LH)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott IMX
Baxter Stratus
Baxter Stratus II
Becton Dickinson Affinity
Boehringer Mannheim ES 300
Ciba Corning ACS 180
Analyte: MHPG Urine
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Analyte: Magnesium
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott Spectrum
Abbott Spectrum EPX
Abbott Spectrum Series II
Abbott Spectrum Series II CCX
American Monitor Diagnostics Excel
American Monitor Diagnostics ISP 1000
American Monitor Diagnostics ISP 2000
American Monitor Diagnostics Perspective
Baxter Paramax
Baxter Paramax 720 ZX
Beckman Astra Ideal
Beckman Synchron CX 4
Beckman Synchron CX 5

Beckman Synchron CX 7
Boehringer Mannheim Hitachi 704
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 747
Ciba Corning 550 Express
Ciba Corning 570 Alliance
Ciba Corning 580 Alliance
Coulter Optichem 120
Coulter Optichem 180
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Dupont Dimension AR
Electronucleonics Gem-Profiler
Electronucleonics Gemini
Electronucleonics Gemstar
Electronucleonics Gemstar II
Instrumentation Laboratories IL Monarch
Instrumentation Laboratories IL Monarch Plus
Kodak Ektachem 400
Kodak Ektachem 500
Kodak Ektachem 700
Kodak Ektachem 700 XR
Kodak Ektachem DT 60
Olympus AU 5000
Olympus Demand
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon AXON
Technicon Assist
Technicon Chem 1
Technicon DAX 24
Technicon DAX 48
Technicon DAX 72
Technicon DAX 96
Technicon RA 1000
Technicon RA 2000
Technicon RA 500
Technicon RA XT
Wako Diagnostics 20R
Wako Diagnostics 30R

Analyte: Osmolality, Serum
Test Category: Osmolality measurements
Test System, Assay or Examination:
Advanced Instruments Osmometer
Fiske 2400 Osmometer
Wescor Colloid Osmometer Model 4420
Wescor Vapor Pressure Osmometer

Analyte: Osmolality, Urine
Test Category: Osmolality measurements
Test System, Assay or Examination:
Advanced Instruments Osmometer
Fiske 2400 Osmometer
Wescor Colloid Osmometer Model 4420
Wescor Vapor Pressure Osmometer

Analyte: Phosphatidylglycerol (PG)—Amniotic Fluid
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Irvine Scientific Aminostat—FLM

Analyte: Phosphorus
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott Spectrum
Abbott Spectrum EPX
Abbott Spectrum Series II
Abbott Spectrum Series II CCX
Abbott VP
American Monitor Diagnostics Excel
American Monitor Diagnostics ISP 1000
American Monitor Diagnostics ISP 2000
American Monitor Diagnostics Perspective
Baxter Paramax
Baxter Paramax 720 ZX
Beckman Astra Ideal
Beckman Synchron AS–X
Beckman Synchron CX 4
Beckman Synchron CX 5
Beckman Synchron CX 7
Boehringer Mannheim Hitachi 704
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 747
Ciba Corning 550 Express
Ciba Corning 570 Alliance
Ciba Corning 580 Alliance
Coulter Optichem 120
Coulter Optichem 180
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Dupont Dimension AR
Electronucleonics Gem-Profiler
Electronucleonics Gemini
Electronucleonics Gemstar
Electronucleonics Gemstar II
Instrumentation Laboratories IL Monarch
Instrumentation Laboratories IL Monarch Plus
Kodak Ektachem 400
Kodak Ektachem 500
Kodak Ektachem 700
Kodak Ektachem 700 XR
Kodak Ektachem DT 60
Olympus AU 5000
Olympus Demand
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon AXON
Technicon Assist
Technicon Chem 1
Technicon DAX 24
Technicon DAX 48
Technicon DAX 72
Technicon DAX 96
Technicon RA 1000
Technicon RA 2000
Technicon RA 500
Technicon RA XT
Wako Diagnostics 20R
Wako Diagnostics 30R

Analyte: Potassium
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
AVL 982–S
AVL 983–S
AVL 984–S
AVL 985–S
AVL 986–S
AVL 987–S
Abbott Spectrum
Abbott Spectrum EPX
Abbott Spectrum Series II
Abbott Spectrum Series II CCX
Abbott VP
Amdev ISE Analyzer
American Monitor Diagnostics Excel
American Monitor Diagnostics ISP 1000
American Monitor Diagnostics ISP 2000
American Monitor Diagnostics Perspective
Ames Clinistat
Ames Seralyzer
Ames Seralyzer III
Baker Ana-Lyte +1
Baker Ana-Lyte +2
Baxter Paramax
Baxter Paramax 720 ZX
Beckman Astra 8
Beckman Astra Ideal
Beckman E2A
Beckman E4A
Beckman LABLYTE 800
Beckman LABLYTE 810
Beckman LABLYTE 820
Beckman LABLYTE 830
Beckman Synchron AS–X
Beckman Synchron CX 3
Beckman Synchron CX 4
Beckman Synchron CX 5
Beckman Synchron CX 7
Beckman Synchron EL–ISE
Boehringer Mannheim Hitachi 704
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 747
Ciba Corning 570 Alliance
Ciba Corning 580 Alliance
Ciba Corning 614
Ciba Corning 644
Ciba Corning 654
Ciba Corning 664 FAST 4
Coulter FLEXLYTE 3

Coulter FLEXLYTE 6
Coulter Optichem 120
Coulter Optichem 180
Dupont Dimension
Dupont Dimension AR
Dupont Na, K, Li Analyzer
Electronucleonics Gem-Profiler
Electronucleonics Gemini
Electronucleonics Gemstar
Electronucleonics Gemstar II
Electronucleonics Starlyte II
Instrumentation Laboratories BGElectrolytes
Instrumentation Laboratories IL 501
Instrumentation Laboratories IL 502
Instrumentation Laboratories IL Monarch
Instrumentation Laboratories IL Monarch Plus
Instrumentation Laboratories Phoenix
Kodak Ektachem 400
Kodak Ektachem 500
Kodak Ektachem 700
Kodak Ektachem 700 XR
Kodak Ektachem DTE Module
Mallinckrodt Gem 6 Plus
Mallinckrodt Gem Premier
Medica Easylite Ion Selective Analyzer
Medica Easylite Plus Ion Selective Analyzer
Olympus AU 5000
Olympus Demand
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon AXON
Technicon Assist
Technicon Chem 1
Technicon DAX 24
Technicon DAX 48
Technicon DAX 72
Technicon DAX 96
Technicon RA 1000
Technicon RA 2000
Technicon RA 500
Technicon RA XT
Wako Diagnostics 20R
Wako Diagnostics 30R

Test Category: Whole blood measurements using teststrip meters (excluding glucose monitoring devices cleared by the FDA specifically for home use)

Test System, Assay or Examination:
Boehringer Mannheim Reflotron Plus

Analyte: Progesterone

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Abbott IMX
Boehringer Mannheim ES 300

Analyte: Prolactin

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Abbott IMX
Baxter Stratus
Baxter Stratus II
Becton Dickinson Affinity
Boehringer Mannheim ES 300
Ciba Corning ACS 180

Analyte: Prostatic Acid Phosphatase

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Abbott IMX
Instrumentation Laboratories IL Monarch Plus

Analyte: Protein, Total

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Abbott Spectrum
Abbott Spectrum EPX
Abbott Spectrum Series II
Abbott Spectrum Series II CCX
Abbott VP
Abbott Vision
American Monitor Diagnostics Excel
American Monitor Diagnostics ISP 1000
American Monitor Diagnostics ISP 2000
American Monitor Diagnostics Perspective
Baxter Paramax
Baxter Paramax 720 ZX
Beckman Synchron AS–X
Beckman Synchron CX 4
Beckman Synchron CX 5
Beckman Synchron CX 7
Boehringer Mannheim Hitachi 704
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 747
Ciba Corning 550 Express
Ciba Corning 570 Alliance
Ciba Corning 580 Alliance
Coulter Optichem 120
Coulter Optichem 180
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Analyst
Dupont Dimension
Dupont Dimension AR
Electronucleonics Gem-Profiler
Electronucleonics Gemini
Electronucleonics Gemstar
Electronucleonics Gemstar II
Instrumentation Laboratories IL Monarch
Instrumentation Laboratories IL Monarch Plus
Instrumentation Laboratories Phoenix
Kodak Ektachem 400
Kodak Ektachem 500
Kodak Ektachem 700
Kodak Ektachem 700 XR
Kodak Ektachem DT 60
Olympus AU 5000
Olympus Demand
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon AXON
Technicon Assist
Technicon Chem 1
Technicon DAX 24
Technicon DAX 48
Technicon DAX 72
Technicon DAX 96
Technicon RA 1000
Technicon RA 2000
Technicon RA 500
Technicon RA XT
Wako Diagnostics 20R
Wako Diagnostics 30R

Analyte: Pseudocholinesterase, Serum

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Dimension

Analyte: Sodium

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
AVL 982–S
AVL 983–S
AVL 984–S
AVL 985–S
AVL 986–S
AVL 987–S
Abbott Spectrum
Abbott Spectrum EPX
Abbott Spectrum Series II
Abbott Spectrum Series II CCX
Abbott VP
Amdev ISE Analyzer
American Monitor Diagnostics Excel
American Monitor Diagnostics ISP 1000
American Monitor Diagnostics ISP 2000
American Monitor Diagnostics Perspective
Baker Ana-Lyte +1
Baker Ana-Lyte +2
Baxter Paramax
Baxter Paramax 720 ZX
Beckman Astra 8
Beckman Astra Ideal
Beckman E2A
Beckman E4A
Beckman LABLYTE 800
Beckman LABLYTE 810
Beckman LABLYTE 820

Beckman LABLYTE 830
Beckman Synchron AS–X
Beckman Synchron CX 3
Beckman Synchron CX 4
Beckman Synchron CX 5
Beckman Synchron CX 7
Beckman Synchron EL–ISE
Boehringer Mannheim Hitachi 704
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 747
Ciba Corning 570 Alliance
Ciba Corning 580 Alliance
Ciba Corning 614
Ciba Corning 644
Ciba Corning 654
Ciba Corning 664 FAST 4
Coulter FLEXLYTE 3
Coulter FLEXLYTE 6
Coulter Optichem 120
Coulter Optichem 180
Dupont Dimension
Dupont Dimension AR
Dupont Na, K, Li Analyzer
Electronucleonics Gem-Profiler
Electronucleonics Gemini
Electronucleonics Gemstar
Electronucleonics Gemstar II
Electronucleonics Starlyte II
Instrumentation Laboratories BGElectrolytes
Instrumentation Laboratories IL 501
Instrumentation Laboratories IL 502
Instrumentation Laboratories IL Monarch
Instrumentation Laboratories IL Monarch Plus
Instrumentation Laboratories Phoenix
Kodak Ektachem 400
Kodak Ektachem 500
Kodak Ektachem 700
Kodak Ektachem 700 XR
Kodak Ektachem DTE Module
Mallinckrodt Gem 6 Plus
Mallinckrodt Gem Premier
Medica Easylite Ion Selective Analyzer
Medica Easylite Plus Ion Selective Analyzer
Olympus AU 5000
Olympus Demand
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon AXON
Technicon Assist
Technicon Chem 1
Technicon DAX 24
Technicon DAX 48
Technicon DAX 72
Technicon DAX 96
Technicon RA 1000
Technicon RA 2000
Technicon RA 500
Technicon RA XT
Wako Diagnostics 20R
Wako Diagnostics 30R

Analyte: Testosterone
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott IMX

Analyte: Thyroid Stimulating Hormone (TSH)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Baxter Stratus
Ciba Corning ACS 180
PB Diagnostics OPUS

Analyte: Thyroid Stimulating Hormone—high sens. (TSH–HS)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott IMX
Baxter Stratus
Becton Dickinson Affinity
Boehringer Mannheim ES 300

Analyte: Thyroxine (T4)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott IMX
Abbott TDX
Abbott TDX FLx
Baxter Stratus
Baxter Stratus II
Becton Dickinson Affinity
Boehringer Mannheim ES 300
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 747
Ciba Corning ACS 180
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Instrumentation Laboratories IL Monarch Plus
PB Diagnostics OPUS
Technicon Chem 1

Analyte: Thyroxine Binding Globulin (TBG)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Boehringer Mannheim ES 300

Analyte: Thyroxine, Free (FT–4)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott IMX
Baxter Stratus
Baxter Stratus II
Boehringer Mannheim ES 300
Ciba Corning ACS 180

Analyte: Triglyceride
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott Spectrum
Abbott Spectrum EPX
Abbott Spectrum Series II
Abbott Spectrum Series II CCX
Abbott TDX
Abbott TDX FLx
Abbott VP
Abbott Vision
American Monitor Diagnostics Excel
American Monitor Diagnostics ISP 1000
American Monitor Diagnostics ISP 2000
American Monitor Diagnostics Perspective
Ames Clinistat
Ames Seralyzer
Ames Seralyzer III
Baxter Paramax
Baxter Paramax 720 ZX
Beckman Astra Ideal
Beckman Synchron AS–X
Beckman Synchron CX 4
Beckman Synchron CX 5
Beckman Synchron CX 7
Boehringer Mannheim Hitachi 704
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 747
Ciba Corning 550 Express
Ciba Corning 570 Alliance
Ciba Corning 580 Alliance
Coulter Optichem 120
Coulter Optichem 180
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Analyst
Dupont Dimension
Dupont Dimension AR
Electronucleonics Gem-Profiler
Electronucleonics Gemini
Electronucleonics Gemstar
Electronucleonics Gemstar II
Instrumentation Laboratories IL Monarch
Instrumentation Laboratories IL Monarch Plus
Kodak Ektachem 400
Kodak Ektachem 500
Kodak Ektachem 700
Kodak Ektachem 700 XR
Kodak Ektachem DT 60
Olympus AU 5000
Olympus Demand
Roche Cobas FARA
Roche Cobas FARA II

Roche Cobas Mira
Roche Cobas Mira S
Technicon AXON
Technicon Assist
Technicon Chem 1
Technicon DAX 24
Technicon DAX 48
Technicon DAX 72
Technicon DAX 96
Technicon RA 1000
Technicon RA 2000
Technicon RA 500
Technicon RA XT
Wako Diagnostics 20R
Wako Diagnostics 30R

Test Category: Whole blood measurements using teststrip meters (excluding glucose monitoring devices cleared by the FDA specifically for home use)

Test System, Assay or Examination:
Boehringer Mannheim Reflotron Plus

Analyte: Triiodothyronine (T–3) Uptake

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Abbott IMX
Abbott TDX
Baxter Stratus
Baxter Stratus II
Becton Dickinson Affinity
Boehringer Mannheim ES 300
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 747
Ciba Corning ACS 180
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Instrumentation Laboratories IL Monarch Plus
Technicon Chem 1

Analyte: Triiodothyronine (T3)

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Abbott IMX
Abbott TDX
Abbott TDX FLx
Baxter Stratus
Baxter Stratus II
Boehringer Mannheim ES 300
Ciba Corning ACS 180
PB Diagnostics OPUS

Analyte: Triiodothyronine, Free (FT–3)

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Ciba Corning ACS 180

Analyte: Urea (BUN)

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Abbott Spectrum
Abbott Spectrum EPX
Abbott Spectrum Series II
Abbott Spectrum Series II CCX
Abbott TDX
Abbott TDX FLx
Abbott VP
Abbott Vision
American Monitor Diagnostics Excel
American Monitor Diagnostics ISP 1000
American Monitor Diagnostics ISP 2000
American Monitor Diagnostics Perspective
Ames Clinistat
Ames Seralyzer
Ames Seralyzer III
Baxter Paramax
Baxter Paramax 720 ZX
Beckman Astra 4
Beckman Astra 8
Beckman Astra Ideal
Beckman BUN Analyzer (Original Model)
Beckman BUN Analyzer 2
Beckman Synchron AS–X
Beckman Synchron CX 3
Beckman Synchron CX 4
Beckman Synchron CX 5
Beckman Synchron CX 7
Boehringer Mannheim Hitachi 704
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 747
Ciba Corning 550 Express
Ciba Corning 570 Alliance
Ciba Corning 580 Alliance
Coulter Optichem 120
Coulter Optichem 180
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Analyst
Dupont Dimension
Dupont Dimension AR
Electronucleonics Gem-Profiler
Electronucleonics Gemini
Electronucleonics Gemstar
Electronucleonics Gemstar II
Instrumentation Laboratories IL Monarch
Instrumentation Laboratories IL Monarch Plus
Instrumentation Laboratories Phoenix
Kodak Ektachem 400
Kodak Ektachem 500
Kodak Ektachem 700
Kodak Ektachem 700 XR
Kodak Ektachem DT 60
Olympus AU 5000
Olympus Demand
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon AXON
Technicon Assist
Technicon Chem 1
Technicon DAX 24
Technicon DAX 48
Technicon DAX 72
Technicon DAX 96
Technicon RA 1000
Technicon RA 2000
Technicon RA 500
Technicon RA XT
Wako Diagnostics 20R
Wako Diagnostics 30R

Test Category: Whole blood measurements using teststrip meters (excluding glucose monitoring devices cleared by the FDA specifically for home use)

Test System, Assay or Examination:
Boehringer Mannheim Reflotron
Boehringer Mannheim Reflotron Plus
Roche Cobas Ready

Analyte: Uric Acid

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Abbott Spectrum
Abbott Spectrum EPX
Abbott Spectrum Series II
Abbott Spectrum Series II CCX
Abbott TDX
Abbott TDX FLx
Abbott VP
Abbott Vision
American Monitor Diagnostics Excel
American Monitor Diagnostics ISP 1000
American Monitor Diagnostics ISP 2000
American Monitor Diagnostics Perspective
Ames Clinistat
Ames Seralyzer
Ames Seralyzer III
Baxter Paramax
Baxter Paramax 720 ZX
Beckman Astra Ideal
Beckman Synchron AS–X
Beckman Synchron CX 4
Beckman Synchron CX 5
Beckman Synchron CX 7
Boehringer Mannheim Hitachi 704
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 747
Ciba Corning 550 Express
Ciba Corning 570 Alliance
Ciba Corning 580 Alliance
Coulter Optichem 120
Coulter Optichem 180
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Analyst

Dupont Dimension
Dupont Dimension AR
Electronucleonics Gem-Profiler
Electronucleonics Gemini
Electronucleonics Gemstar
Electronucleonics Gemstar II
Instrumentation Laboratories IL Monarch
Instrumentation Laboratories IL Monarch Plus
Kodak Ektachem 400
Kodak Ektachem 500
Kodak Ektachem 700
Kodak Ektachem 700 XR
Kodak Ektachem DT 60
Olympus AU 5000
Olympus Demand
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira S
Technicon AXON
Technicon Assist
Technicon Chem 1
Technicon DAX 24
Technicon DAX 48
Technicon DAX 72
Technicon DAX 96
Technicon RA 1000
Technicon RA 2000
Technicon RA 500
Technicon RA XT
Wako Diagnostics 20R
Wako Diagnostics 30R

Test Category: Whole blood measurements using teststrip meters (excluding glucose monitoring devices cleared by the FDA specifically for home use)

Test System, Assay or Examination:
Boehringer Mannheim Reflotron
Boehringer Mannheim Reflotron Plus

Analyte: Vitamin B12

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Abbott IMX
Abbott TDX FLx
Ciba Corning ACS 180

Analyte: Zinc Protoporphyrin

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
AVIV Hematofluorometer
Helena Protofluor

Analyte: pH

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
AVL 987–S
Beckman LABLYTE 820
Ciba Corning 634
Coulter FLEXLYTE 6

Speciality/Subspeciality: General Immunology

Analyte: Allergen specific IgE

Test Category: Manual procedures with limited steps and limited sample or reagent preparation

Test System, Assay or Examination:
Quidel Allergen Screen
Quidel Food Allergen Screen

Analyte: Alpha-1-Acid Glycoprotein (orosomucoid)

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Beckman Array 360

Analyte: Alpha-1-Antitrypsin

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Beckman Array 360
Instrumentation Laboratories IL Monarch Plus

Analyte: Alpha-2-Macroglobulin

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Beckman Array 360

Analyte: Alpha-Fetoprotein—Tumor Marker

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Abbott IMX

Analyte: Aminoglycosides

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Abbott TDX

Analyte: Anti-DNA Antibodies

Test Category: Manual procedures with limited steps and limited sample or reagent preparation

Test System, Assay or Examination:
General Biometrics ImmunoDot Autoimmunity Screening Panel
Stanbio SLE Quicktest

Analyte: Anti-DNP antibodies

Test Category: Manual procedures with limited steps and limited sample or reagent preparation

Test System, Assay or Examination:
Ampcor SLE Test
Diagnostic Technology ANA Check
Fisher Diagnostic SLE Latex Test Kit
Hycor Serascan SLE

Analyte: Anti-Nuclear Antibodies (ANA)

Test Category: Manual procedures with limited steps and limited sample or reagent preparation

Test System, Assay or Examination:
General Biometrics ImmunoDot Autoimmunity Screening Panel
Whittaker Bioproducts RheumaStrip

Analyte: Anti-RNP (Ribonucleoprotein)

Test Category: Manual procedures with limited steps and limited sample or reagent preparation

Test System, Assay or Examination:
General Biometrics ImmunoDot Autoimmunity Screening Panel

Analyte: Anti-SS-A/Ro

Test Category: Manual procedures with limited steps and limited sample or reagent preparation

Test System, Assay or Examination:
General Biometrics ImmunoDot Autoimmunity Screening Panel

Analyte: Anti-SS-B/La

Test Category: Manual procedures with limited steps and limited sample or reagent preparation

Test System, Assay or Examination:
General Biometrics ImmunoDot Autoimmunity Screening Panel

Analyte: Anti-Sm (Smith)

Test Category: Manual procedures with limited steps and limited sample or reagent preparation

Test System, Assay or Examination:
General Biometrics ImmunoDot Autoimmunity Screening Panel

Analyte: Anti-Streptolysin O (ASO)

Test Category: Manual procedures with limited steps and limited sample or reagent preparation

Test System, Assay or Examination:
Ampcor Quik-Dot
Behring RapiTex
Biokit Rheumagen ASO
Diagnostic Technology ASO Check
Fisher Diagnostic LAtest ASO
Seradyn Color Slide
V-Tech V-Trend ASO Plus
Wampole Streptozyme

Analyte: Anti-Thyroglobulin Antibodies (ATA)

Test Category: Manual procedures with limited steps and limited sample or reagent preparation

Test System, Assay or Examination:
General Biometrics ImmunoDot Thyroid Autoimmunity Panel

Analyte: Anti-Thyroid Microsomal Antibodies (AMA)

Test Category: Manual procedures with limited steps and limited sample or reagent preparation

Test System, Assay or Examination:
General Biometrics ImmunoDot Thyroid Autoimmunity Panel

Analyte: Beta-2 microglobulin

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Abbott IMX

Analyte: C–Reactive Protein (CRP)

Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Abbott Vision
Beckman Array 360
Beckman Synchron CX 7
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Technicon Chem 1
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Ampcor Quik-Dot
Amtec CRP
Baxter ImmunoSCAN
Behring RapiTex
Biokit Rheumagen CRP
Diagnostic Technology CRP Check
Difco Bacto CRP Slide Test Set
Fisher Diagnostic LAtest CRP
Hycor Serascan CRP
Sclavo CRP Latex Test
Seradyn Color Slide
Stanbio CRP Quicktest
V-Tech Target CRP
Wampole Immunex CRP
Analyte: Carcinoembryonic Antigen (CEA)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott IMX
Analyte: Ceruloplasmin
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Beckman Array 360
Analyte: Coccidioides Antibodies
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Immuno-Mycologics LA-Cocci Antibody System
Meridian Diagnostics Coccidiodes Latex Agglutination System
Analyte: Complement C3
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Beckman Array 360
Boehringer Mannheim Hitachi 717
Instrumentation Laboratories IL Monarch Plus
Technicon Chem 1
Analyte: Complement C4
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Beckman Array 360
Boehringer Mannheim Hitachi 717
Instrumentation Laboratories IL Monarch Plus
Technicon Chem 1
Analyte: Cytomegalovirus Antibodies (IgG/IgM)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott IMX
PB Diagnostics OPUS
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Becton Dickinson CMV Scan
Disease Detection International SeroCard CMV IgG Test
General Biometrics ImmunoDot Preconception Screening Panel
Meridian Diagnostics Immunocard Test
V–Tech Target CMV
Analyte: Febrile Agglutinins
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Becton Dickinson BBL—Slide Test
Difco Bacto-Slide Test
Gamma Biologicals Slide Test
Analyte: Fungus Antibodies
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Immuno-Mycologics LA–Sporo Antibody System
Analyte: Haptoglobin
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Beckman Array 360
Instrumentation Laboratories IL Monarch Plus
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Behring RapiTex
Analyte: Helicobacter pylori Antibodies
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Quidel H. pylori Test
Analyte: Hepatitis A Antibody (HAVAb)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott IMX
Analyte: Hepatitis B Core Antibody (Hb Core)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott IMX
Analyte: Hepatitis B Surface Antigen (HBS Ag)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott IMX
Analyte: Herpes simplex I and/or II Antibodies
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Disease Detection International SeroCard HSV IgG Test
General Biometrics ImmunoDot Preconception Screening Panel
Meridian Diagnostics Immunocard Test
Analyte: Histoplasma Antibodies
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Immuno-Mycologics LA–Histo Antibody System
Analyte: Immunoglobulins IgA
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Beckman Array 360
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Dupont ACA
Dupont ACA IV
Dupont ACA V
Instrumentation Laboratories IL Monarch Plus
Technicon Chem 1
Analyte: Immunoglobulins IgE
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott IMX
Baxter Stratus
Baxter Stratus II
Boehringer Mannheim ES 300
Ciba Corning ACS 180

Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Quidel Total IgE Test
Analyte: Immunoglobulins IgG
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Beckman Array 360
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Dupont ACA
Dupont ACA IV
Dupont ACA V
Instrumentation Laboratories IL Monarch Plus
Technicon Chem 1
Analyte: Immunoglobulins IgM
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Beckman Array 360
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Dupont ACA
Dupont ACA IV
Dupont ACA V
Instrumentation Laboratories IL Monarch Plus
Technicon Chem 1
Analyte: Infectious Mononucleosis Antibodies (Mono)
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Ampcor Quik-Dot
Baxter ImmunoSCAN (Latex)
Baxter ImmunoSCAN RBC
Biokit Monogen
Diagnostic Technology Infectious Mononucleosis Check
General Biometrics ImmunoDot Infectious Mono Syndrome Panel
Gull Laboratories Mono-Lex Test
Hybritech Concise Mono Test
Hycor Serascan Infectious Mononucleosis Test
Leeco Diagnostics Preview Mono
Medical Technology Corp. Mono-Lisa
Medical Technology Corp. Optitec Mono
Organon NML Monosticon
Ortho Monolert
Ortho Monospot
Pacific Biotech Cards
Sclavo Infectious Mononucleosis Screening
Seradyn Color Slide II
Unipath Oxoid Infectious Mononucleosis Test
V-Tech Target Mono
V-Tech V-Trend Kit IM
Ventrex
Wampole Mono-Diff
Wampole Mono-Latex
Wampole Mono-Sure
Wampole Mono-Test
Analyte: Kappa Light Chains
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Beckman Array 360
Analyte: Lambda Light Chains
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Beckman Array 360
Analyte: Lyme Disease Antibodies (Borrelia burgdorferi Abs
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
General Biometrics ImmunoDot Lyme Disease Panel
Quidel Lyme Disease Test
Analyte: Mycoplasma pneumonia Antibodies
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Medical Diag Technologies Mycoplasma pneumonia IgG Ab Test
Meridian Diagnostics Meristar-MP
Analyte: Prealbumin
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Beckman Array 360
Analyte: Properdin Factor B
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Beckman Array 360
Analyte: Prostatic Specific Antigen (PSA)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott IMX
Analyte: Rheumatoid Factor (RA)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Beckman Array 360
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Ampcor Quik-Dot
Amtec RF
Baxter ImmunoSCAN (Latex)
Baxter ImmunoSCAN RBC
Becton Dickinson Macro-vue RF
Behring RapiTex
Biokit Rheumagen RF
Diagnostic Technology RA Check
Difco Bacto RF Test
Fisher Diagnostic LAtest RF
General Biometrics ImmunoDot Autoimmunity Screening Panel
Hycor Serascan RA test
Organon Rheumanosticon Dri-Dot
Sclavo Reuma Test
Seradyn Seratest RF Latex Test
Stanbio RA Factor Quicktest
Wampole Rheumatex
Wampole Rheumaton
Analyte: Rubella Antibodies, IgG/IgM
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott IMX
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Becton Dickinson Rubascan
Biokit Rubagen
Disease Detection International SeroCard Rubella IgG Test
General Biometrics ImmunoDot Preconception Screening Panel
General Biometrics ImmunoDot Quantitative Rubella
Meridian Diagnostics Immunocard Test
Murex SUDS Rubella
V-Tech Target Rubella
Wampole Virogen Rubella Micro Latex Test
Wampole Virogen Rubella Slide Test
Analyte: Toxoplasma gondii Antibodies (IgG/IgM)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott IMX
PB Diagnostics OPUS
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Bio-Medical BIOCARD Toxo Ab
Disease Detection International SeroCard Toxoplasma IgG
General Biometrics ImmunoDot Preconception Screening Panel

Meridian Diagnostics Immunocard Test
Murex SUDS Toxo
Analyte: Transferrin
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Beckman Array 360
Boehringer Mannheim Hitachi 717
Instrumentation Laboratories IL Monarch Plus
Technicon Chem 1
Analyte: Treponema pallidum Antibodies
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Ampcor RPR
Ampcor TRUST RPR
Becton Dickinson Macro-vue RPR
Fisher Diagnostic Reagin Screen Test
New Horizons TRUST assay
Seradyn Color Slide
Analyte: Varicella-Zoster Virus Antibodies
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Becton Dickinson VZV Scan
Speciality/Subspeciality: Hematology
Analyte: Activated Partial Thromboplastin Time (APTT)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
American Scientific Fibrometer
Becton Dickinson BBL Fibrometer
BioData Microsample Coagulation Analyzer
Ciba Corning Biotrack 512
General Diagnostics Coag-A-Mate
General Diagnostics Coag-A-Mate X2
General Diagnostics Coag-A-Mate XC
Helena Cascade 480
Helena Laboratories Dataclot
Instrumentation Laboratories IL ACL 100
Instrumentation Laboratories IL ACL 1000
Instrumentation Laboratories IL ACL 200
Instrumentation Laboratories IL ACL 2000
Instrumentation Laboratories IL ACL 300
Instrumentation Laboratories IL ACL 3000
Instrumentation Laboratories IL ACL 3000 Plus
Instrumentation Laboratories IL ACL 810
Medical Laboratories MLA Electra 1000 C
Medical Laboratories MLA Electra 700
Medical Laboratories MLA Electra 750
Medical Laboratories MLA Electra 800
Medical Laboratories MLA Electra 900
Medical Laboratories MLA Electra 900 C
Organon Teknika Coag-A-Mate Data-Mate
Organon Teknika Coag-A-Mate RA4
Organon Teknika Coag-A-Mate X–2
Organon Teknika Coag-A-Mate XC
Organon Teknika Coag-A-Mate XC Plus
Organon Teknika Coag-A-Mate XM
Ortho Koagulab 16S
Ortho Koagulab 32S
Ortho Koagulab 40–A
Sigma AccuStasis 1000
Sigma AccuStasis 2000
Sysmex CA–5000
Analyte: Antithrombin III (ATIII)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Beckman Array 360
Dupont ACA
Dupont ACA IV
Dupont ACA V
Analyte: Fibrin Split Products (Fibrin Degradation)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Dupont ACA IV
Dupont ACA V
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
American Diagnostics Dimertest
Analyte: Fibrinogen
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Becton Dickinson BBL Fibrometer
Dupont ACA IV
Dupont ACA V
General Diagnostics Coag-A-Mate X2
General Diagnostics Coag-A-Mate XC
Helena Cascade 480
Instrumentation Laboratories IL ACL 100
Instrumentation Laboratories IL ACL 200
Instrumentation Laboratories IL ACL 2000
Instrumentation Laboratories IL ACL 300
Instrumentation Laboratories IL ACL 3000
Instrumentation Laboratories IL ACL 3000 Plus
Instrumentation Laboratories IL ACL 810
Medical Laboratories MLA Electra 700
Medical Laboratories MLA Electra 750
Medical Laboratories MLA Electra 800
Organon Teknika Coag-A-Mate RA4
Organon Teknika Coag-A-Mate XC
Organon Teknika Coag-A-Mate XM
Ortho Koagulab 16S
Ortho Koagulab 32S
Ortho Koagulab 40–A
Analyte: Hematocrit
Test Category: Automated hematology procedures with differentials that do not require operator intervention during the analytic process and that do not require an analyst to interpret a histogram or scattegram
Test System, Assay or Examination:
Baker 9000
Coulter JS
Coulter JT
Coulter JT2
Coulter JT3
Coulter MAXM
Coulter S Plus IVW/DIF
Coulter S Plus VI/STKR
Coulter STKR
Coulter STKS
Coulter T540
Coulter T660
Coulter T890
Roche Cobas Argos
Roche Cobas Minos STX
Test Category: Automated hematology procedures without differentials that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Baker 8000
Becton Dickinson QBC AutoRead
Coulter 530
Coulter 560
Coulter 770
Coulter CBC4
Coulter CBC5
Coulter M430
Coulter S Plus
Coulter S Plus II
Coulter S Plus III
Coulter S Plus IV
Coulter S Plus Jr.
Coulter S Plus V
Coulter S550
Coulter S880
Coulter ST
Electronucleonics Cellstar
Ortho ELT 15
Ortho ELT 1500
Ortho ELT 8
Ortho ELT 8/DS
Ortho ELT 8/WS
Ortho ELT 800/WS
Roche Cobas Minos STE
Sequoia Turner 1600
Sequoia Turner 700

Sequoia Turner 900
Sysmex CC–130
Sysmex CC–150
Sysmex CC–180
Sysmex CC–700
Sysmex CC–720
Sysmex CC–780
Sysmex E–2500
Sysmex E–5000
Sysmex K–1000
Sysmex NE–8000

Analyte: Hemoglobin
Test Category: Automated hematology procedures with differentials that do not require operator intervention during the analytic process and that do not require an analyst to interpret a histogram or scattegram
Test System, Assay or Examination:
Baker 9000
Coulter JS
Coulter JT
Coulter JT2
Coulter JT3
Coulter MAXM
Coulter S Plus IVW/DIF
Coulter S Plus VI/STKR
Coulter STKR
Coulter STKS
Coulter T540
Coulter T660
Coulter T890
Roche Cobas Argos
Roche Cobas Minos STX

Test Category: Automated hematology procedures without differentials that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Baker 8000
Becton Dickinson QBC AutoRead
Coulter 530
Coulter 560
Coulter 770
Coulter CBC4
Coulter CBC5
Coulter M430
Coulter S Plus
Coulter S Plus II
Coulter S Plus III
Coulter S Plus IV
Coulter S Plus Jr.
Coulter S Plus V
Coulter S550
Coulter S880
Coulter ST
Electronucleonics Cellstar
Hemocue Hemoglobin System
Ortho ELT 15
Ortho ELT 1500
Ortho ELT 8
Ortho ELT 8/DS
Ortho ELT 8/WS
Ortho ELT 800/WS
Roche Cobas Minos STE
Sequoia Turner 1600
Sequoia Turner 700
Sequoia Turner 900
Sysmex CC–130
Sysmex CC–150
Sysmex CC–180
Sysmex CC–700
Sysmex CC–720
Sysmex CC–780
Sysmex E–2500
Sysmex E–5000
Sysmex K–1000
Sysmex NE–8000

Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott Vision
Ames Seralyzer
Ames Seralyzer III
Kodak Ektachem DT 60
LEO Diagnostics Hemocue

Test Category: Whole blood measurements using teststrip meters (excluding glucose monitoring devices cleared by the FDA specifically for home use)
Test System, Assay or Examination:
Boehringer Mannheim Reflotron Plus

Analyte: Heparin
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Dupont ACA IV
Dupont ACA V

Analyte: Plasminogen
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Dupont ACA IV
Dupont ACA V

Analyte: Platelet Count
Test Category: Automated hematology procedures with differentials that do not require operator intervention during the analytic process and that do not require an analyst to interpret a histogram or scattegram
Test System, Assay or Examination:
Baker 9000
Coulter JS
Coulter JT
Coulter JT2
Coulter JT3
Coulter MAXM
Coulter S Plus IVW/DIF
Coulter S Plus VI/STKR
Coulter STKR
Coulter STKS
Coulter T540
Coulter T660
Coulter T890
Roche Cobas Argos
Roche Cobas Minos STX

Test Category: Automated hematology procedures without differentials that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Baker 8000
Becton Dickinson QBC AutoRead
Coulter S Plus
Coulter S Plus II
Coulter S Plus III
Coulter S Plus IV
Coulter S Plus Jr.
Coulter S Plus V
Coulter S880
Coulter ST
Electronucleonics Cellstar
Ortho ELT 15
Ortho ELT 1500
Ortho ELT 8
Ortho ELT 8/DS
Ortho ELT 8/WS
Ortho ELT 800/WS
Roche Cobas Minos STE
Sequoia Turner 1600
Sysmex CC–130
Sysmex CC–150
Sysmex CC–180
Sysmex CC–700
Sysmex CC–720
Sysmex CC–780
Sysmex E–2500
Sysmex E–5000
Sysmex K–1000
Sysmex NE–8000

Analyte: Prothrombin Time (PT)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott Vision
American Scientific Fibrometer
Becton Dickinson BBL Fibrometer
BioData Microsample Coagulation Analyzer
Ciba Corning Biotrack 512
General Diagnostics Coag-A-Mate
General Diagnostics Coag-A-Mate X2
General Diagnostics Coag-A-Mate XC
Helena Cascade 480
Helena Laboratories Dataclot
Instrumentation Laboratories IL ACL 100
Instrumentation Laboratories IL ACL 1000
Instrumentation Laboratories IL ACL 200
Instrumentation Laboratories IL ACL 2000
Instrumentation Laboratories IL ACL 500
Instrumentation Laboratories IL ACL 3000
Instrumentation Laboratories IL ACL 3000 Plus
Instrumentation Laboratories IL ACL 810
Medical Laboratories MLA Electra 1000 C
Medical Laboratories MLA Electra 700

Medical Laboratories MLA Electra 750
Medical Laboratories MLA Electra 800
Medical Laboratories MLA Electra 900
Medical Laboratories MLA Electra 900 C
Organon Teknika Coag-A-Mate Data-Mate
Organon Teknika Coag-A-Mate RA4
Organon Teknika Coag-A-Mate X–2
Organon Teknika Coag-A-Mate XC
Organon Teknika Coag-A-Mate XC Plus
Organon Teknika Coag-A-Mate XM
Ortho Koagulab 16S
Ortho Koagulab 32S
Ortho Koagulab 40–A
Sigma AccuStasis 1000
Sigma AccuStasis 2000
Sysmex CA–5000

Analyte: Red Blood Cell Count (Erythrocyte Count)

Test Category: Automated hematology procedures with differentials that do not require operator intervention during the analytic process and that do not require an analyst to interpret a histogram or scattegram

Test System, Assay or Examination:
Baker 9000
Coulter JS
Coulter JT
Coulter JT2
Coulter JT3
Coulter MAXM
Coulter S Plus IVW/DIF
Coulter S Plus VI/STKR
Coulter STKR
Coulter STKS
Coulter T540
Coulter T660
Coulter T890
Roche Cobas Argos
Roche Cobas Minos STX

Test Category: Automated hematology procedures without differentials that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Baker 8000
Becton Dickinson QBC AutoRead
Coulter 530
Coulter 560
Coulter 770
Coulter CBC4
Coulter CBC5
Coulter M430
Coulter S Plus
Coulter S Plus II
Coulter S Plus III
Coulter S Plus IV
Coulter S Plus Jr.
Coulter S Plus V
Coulter S550
Coulter S880
Coulter ST
Electronucleonics Cellstar
Ortho ELT 15
Ortho ELT 1500
Ortho ELT 8
Ortho ELT 8/DS
Ortho ELT 8/WS
Ortho ELT 800/WS
Roche Cobas Minos STE
Sequoia Turner 1600
Sequoia Turner 700
Sequoia Turner 900
Sysmex CC–130
Sysmex CC–150
Sysmex CC–180
Sysmex CC–700
Sysmex CC–720
Sysmex CC–780
Sysmex E–2500
Sysmex E–5000
Sysmex K–1000
Sysmex NE–8000

Analyte: Thrombin Time

Test Category: Automated procedures that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Helena Cascade 480
Organon Teknika Coag-A-Mate RA4
Organon Teknika Coag-A-Mate XM

Analyte: White Blood Cell (WBC) Differential

Test Category: Automated hematology procedures with differentials that do not require operator intervention during the analytic process and that do not require an analyst to interpret a histogram or scattegram

Test System, Assay or Examination:
Baker 9000
Coulter JS
Coulter JT
Coulter JT2
Coulter JT3
Coulter MAXM
Coulter S Plus IVW/DIF
Coulter S Plus VI/STKR
Coulter STKR
Coulter STKS
Coulter T540
Coulter T660
Coulter T890
Roche Cobas Argos
Roche Cobas Minos STX

Test Category: Manual WBC differential; analyst not required to identify atypical cells

Test System, Assay or Examination: All Test Systems, Assays or Examinations

Analyte: White Blood Cell Count (Leukocyte Count)

Test Category: Automated hematology procedures with differentials that do not require operator intervention during the analytic process and that do not require an analyst to interpret a histogram or scattegram

Test System, Assay or Examination:
Baker 9000
Coulter JS
Coulter JT
Coulter JT2
Coulter JT3
Coulter MAXM
Coulter S Plus IVW/DIF
Coulter S Plus VI/STKR
Coulter STKR
Coulter STKS
Coulter T540
Coulter T660
Coulter T890
Roche Cobas Argos
Roche Cobas Minos STX

Test Category: Automated hematology procedures without differentials that do not require operator intervention during the analytic process

Test System, Assay or Examination:
Baker 8000
Becton Dickinson QBC AutoRead
Coulter 530
Coulter 560
Coulter 770
Coulter CBC4
Coulter CBC5
Coulter M430
Coulter S Plus
Coulter S Plus II
Coulter S Plus III
Coulter S Plus IV
Coulter S Plus Jr.
Coulter S Plus V
Coulter S550
Coulter S880
Coulter ST
Electronucleonics Cellstar
Ortho ELT 15
Ortho ELT 1500
Ortho ELT 8
Ortho ELT 8/DS
Ortho ELT 8/WS
Ortho ELT 800
Ortho ELT 800/WS
Roche Cobas Minos STE
Sequoia Turner 1600
Sequoia Turner 700
Sequoia Turner 900
Sysmex CC–130
Sysmex CC–150
Sysmex CC–180
Sysmex CC–700
Sysmex CC–720
Sysmex CC–780
Sysmex E–2500
Sysmex E–5000
Sysmex K–1000
Sysmex NE–8000

Speciality/Subspeciality: Immunohematology

Analyte: ABO group—RBC

Test Category: Manual procedures with limited steps and limited sample or reagent preparation

Test System, Assay or Examination:
Amtec Anti-A, Anti-B, Anti-A,B (slide, tube)
Amtec Anti-A1 Lectin (slide, tube)
Amtec CM-Tec Anti-A, Anti-B, Anti-

A,B (microwell)
Amtec CM-Tec Anti-A, Anti-B, Anti-A,B (tube)
BCA Anti-A, Anti-B, Anti-A,B (microplate)
BCA Anti-A, Anti-B, Anti-A,B (slide, tube)
BCA Anti-A1 Lectin (slide, tube)
Dade Anti-A, Anti-B, Anti-A,B (microplate)
Dade Anti-A, Anti-B, Anti-A,B (slide, tube)
Dade Mono-Type Anti-A, Anti-B, Anti-A+B (microplate)
Dade Mono-Type Anti-A, Anti-B, Anti-A+B (slide, tube)
Gamma Anti-A, Anti-B, Anti-A,B (slide, tube)
Gamma Anti-A1 Lectin (slide, tube)
Gamma Omni-Series II Anti-A, Anti-B, Anti-A,B (microwell)
Gamma Omni-Series II Anti-A, Anti-B, Anti-A,B (tube)
Gamma's Gamma-clone Anti-A, Anti-B, Anti-A+B (microwell)
Gamma's Gamma-clone Anti-A, Anti-B, Anti-A+B (slide, tube)
Immucor Anti-A, Anti-B, Anti-A,B (microplate)
Immucor Anti-A, Anti-B, Anti-A,B (slide, tube)
Immucor Anti-A, Anti-B, Anti-A,B—murine (microplate)
Immucor Anti-A, Anti-B, Anti-A,B—murine (slide, tube)
Immucor Anti-A1 (slide, tube)
Ortho Anti-A1 Lectin (slide, tube)
Ortho BioClone Anti-A, Anti-B, Anti-A+B (microplate)
Ortho BioClone Anti-A, Anti-B, Anti-A+B (slide, tube)

Analyte: ABO group confirmation—Serum, Plasma
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Amtec Serum Grouping Cells
BCA Confirmcells and Versa Cells
Dade Reverse-Cyte (microplate)
Dade Reverse-Cyte (tube)
Gamma Reverse Group (microwell)
Gamma Reverse Group (tube)
Immucor Referencells
Ortho Affirmagen

Analyte: D(Rho) Type
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Amtec Anti-D (slide, rapid tube)
Amtec CM-Tec Anti-D (microwell)
Amtec CM-Tec Anti-D (slide, saline tube)
BCA Anti-D (saline tube)
BCA Anti-D (slide, rapid tube)
BCA UltraSera Anti-D (microplate)
BCA UltraSera Anti-D (slide, tube)
Dade Anti-D (microplate)
Dade Anti-D (slide, rapid tube)
Dade Chemically Modified Anti-D (microplate)
Dade Chemically Modified Anti-D (slide, tube)
Gamma Anti-D (saline tube)
Gamma Anti-D (slide, modified tube)
Gamma RST/Omni-Series II Anti-D (microwell)
Gamma RST/Omni-Series II Anti-D (slide. saline tube)
Gamma's Gamma-clone Anti-D (microwell)
Gamma's Gamma-clone Anti-D (slide, tube)
Immucor Anti-D (microplate)
Immucor Anti-D (saline tube)
Immucor Anti-D (slide, tube)
Immucor Anti-D Chem-D (microplate)
Immucor Anti-D Chem-D (slide, tube)
Ortho Anti-D (slide, modified tube)
Ortho BioClone Anti-D (microplate)
Ortho BioClone Anti-D (slide, rapid tube)

Analyte: Du (Weak D RBC antigen)
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Amtec Anti-D
Amtec CM-Tec Anti-D
BCA Anti-D
BCA UltraSera Anti-D
Dade Anti-D
Dade Chemically Modified Anti-D
Gamma Anti-D
Gamma RST/Omni-Series II Anti-D
Gamma's Gamma-clone Anti-D
Immucor Anti-D
Immucor Anti-D Chem-D
Ortho Anti-D
Ortho BioClone Anti-D

Analyte: RBC antigen type other than A or B
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Amtec Anti-H Lectin
Amtec Anti-N Lectin
Amtec Blood Grouping Reagents (microwell)
Amtec Blood Grouping Reagents (slide, tube)
Amtec Blood Grouping Reagents for Indirect Antiglobulin
BCA Anti-H Lectin
BCA Anti-N Lectin
BCA Blood Grouping Reagents (slide, tube)
BCA Blood Grouping Reagents for Indirect Antiglobulin Test
Dade Blood Grouping Reagents (slide, tube)
Dade Blood Grouping Reagent Chemically Modified (slide, tube)
Dade Blood Grouping Reagents for Indirect Antiglobulin Test
Dade Lectin-H
Gamma Anti-H Lectin
Gamma Anti-N Lectin
Gamma Blood Grouping Reagents (slide, tube)
Gamma Blood Grouping Reagents for Indirect Antiglobulin
Gamma RST-Series Blood Grouping Reagents (slide, tube)
Gamma's Gamma ID-series Blood Grouping Reagents
Gamma's Gamma-clone Blood Grouping Reagents (microwell)
Gamma's Gamma-clone Blood Grouping Reagents (tube)
Immucor Anti-N Lectin
Immucor Blood Grouping Reagents (microplate)
Immucor Blood Grouping Reagents (slide, tube)
Immucor Blood Grouping Reagents—Indirect Antiglobulin
Ortho BioClone Blood Grouping Reagents
Ortho Blood Grouping Reagents (slide, tube)
Ortho Blood Grouping Reagents for Indirect Antiglobulin Test

Analyte: Unexpected RBC antibody—detection—serum
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Amtec Screening Cells—SAL/ALB/LISS/PEG/IAT
BCA Bio-Cells—SAL/ALB/LISS/PEG/IAT
BCA Spectrogen—SAL/ALB/LISS/PEG/IAT
Dade Search-Cyte—SAL/ALB/LISS/PEG/IAT
Dade Search-Cyte Plus—SAL/ALB/LISS/PEG/IAT
Dade Search-Cyte TCS—SAL/ALB/LISS/PEG/IAT
Gamma Duet—SAL/ALB/LISS/PEG/IAT
Gamma Pool—SAL/ALB/LISS/PEG/IAT
Gamma Trio—SAL/ALB/LISS/PEG/IAT
Gamma r-set—SAL/ALB/LISS/PEG/IAT
Immucor Hemantigen—SAL/ALB/LISS/PEG/IAT
Immucor Panoscreen—SAL/ALB/LISS/PEG/IAT
Ortho Pooled Screening Cells—SAL/ALB/LISS/PEG/IAT
Ortho Selectogen—SAL/ALB/LISS/PEG/IAT
Ortho Surgiscreen—SAL/ALB/LISS/PEG/IAT

Speciality/Subspeciality: Mycobacteriology
Analyte: Acid-fast bacteria
Test Category: Direct acid fast smear

Test System, Assay or Examination: All Test Systems, Assays or Examinations
Speciality/Subspeciality: Mycology
Analyte: All fungi
Test Category: Primary culture inoculation
Test System, Assay or Examination: All Test Systems, Assays or Examinations
Analyte: Candida
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Becton Dickinson Directigen 1–2–3 Disseminated Candidiasis
Analyte: Cryptococcus
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Baxter MYCO-Immune Cryptococal Ag Latex Agg (direct Ag)
Meridian Cryptococcal Antigen Latex Agg. System (dir Ag)
Meridian Diagnostics Premier Cryptococcal Antigen (dir Ag)
Analyte: Dermatophytes
Test Category: Tests using selective media for presence or absence of Dermatophytes
Test System, Assay or Examination:
Becton Dickinson BBL Dermatophyte Test Medium
Carr-Scarborough Dermatophyte Test Medium
Hardy Diagnostics Dermatophyte Test Medium
Incstar Dermatophyte Test Medium
Medical Technology Corp. Oricult DTM
Analyte: Fungal elements
Test Category: Microscopic evaluation of KOH preparations
Test System, Assay or Examination: All Test Systems, Assays or Examinations
Analyte: Yeast
Test Category: Automated mycology procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Vitek Systems VITEK Yeast Biochemical Card
Test Category: ID of C. albican (excluding semi-automated & semi-quant. procedures)
Test System, Assay or Examination:
Analytab API 20C Yeast Identification Kits
Analytab API Germ Tube
Analytab Yeast Ident
Baxter MicroScan Rapid Yeast Identification Panel
Carr-Scarborough C. albicans Disc Screening Kit
Culture Kits, Inc. CandiKit
Innovative Diagnostic Systems IDS Rapid SS/U System
Medical Wire Equip. MicroRing YT
Test Category: Isolation of yeast with identification limited to Candida albicans
Test System, Assay or Examination: All Test Systems, Assays or Examinations
Speciality/Subspeciality: Parasitology
Analyte: Enterobius vermicularis
Test Category: Microscopic evaluation of pinworm preparations
Test System, Assay or Examination: All Test Systems, Assays or Examinations
Analyte: Intestinal parasites
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Alexon Biomedical ProSpect Giardia Antibodies Inc. Giard EIA
Test Category: Microscopic evaluation of direct wet mount preparations
Test System, Assay or Examination: All Test Systems, Assays or Examinations
Analyte: Trichomonas
Test Category: Microscopic evaluation of direct wet mount preparations
Test System, Assay or Examination: All Test Systems, Assays or Examinations
Speciality/Subspeciality: Toxicology/TDM
Analyte: Acetaminophen
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott ADX
Abbott TDX
Abbott TDX FLx
Dupont ACA
Dupont ACA IV
Dupont ACA V
Instrumentation Laboratories IL Monarch Plus
Analyte: Amikacin
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Baxter Stratus
Baxter Stratus II
Dupont ACA
Dupont ACA IV
Dupont ACA V
Instrumentation Laboratories IL Monarch Plus
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Analyte: Amphetamines
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott ADX
Abbott TDX
Abbott TDX FLx
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Instrumentation Laboratories IL Monarch Plus
Analyte: Barbiturates
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott ADX
Abbott TDX
Abbott TDX FLx
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Instrumentation Laboratories IL Monarch Plus
Analyte: Benzodiazepines
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott ADX
Abbott TDX
Abbott TDX FLx
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Instrumentation Laboratories IL Monarch Plus
Analyte: Cannabinoids
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott ADX
Abbott TDX
Abbott TDX FLx
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Instrumentation Laboratories IL Monarch Plus
Analyte: Carbamazepine
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Ames Seralyzer III
Baxter Stratus
Baxter Stratus II
Beckman Array 360

Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Instrumentation Laboratories IL Monarch Plus
PB Diagnostics OPUS
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S

Analyte: Carbamazepine, Free
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx

Analyte: Cocaine Metabolites
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott ADX
Abbott TDX
Abbott TDX FLx
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Instrumentation Laboratories IL Monarch Plus

Analyte: Cyclosporine
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Dupont ACA
Dupont ACA IV
Dupont ACA V

Analyte: Digitoxin
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Baxter Stratus
Baxter Stratus II
Dupont ACA IV
Dupont ACA V

Analyte: Digoxin
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Ames Clinimate—TDA
Ames Seralyzer III
Baxter Stratus
Baxter Stratus II
Beckman Synchron CX 4
Beckman Synchron CX 5
Becton Dickinson Affinity
Boehringer Mannheim ES 300
Ciba Corning ACS 180
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Instrumentation Laboratories IL Monarch Plus
PB Diagnostics OPUS
Technicon Chem 1

Analyte: Disopyramide
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx

Analyte: Drugs of Abuse in Urine
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abuscreen ONTRAK

Analyte: Ethanol (Alcohol)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott ADX
Abbott TDX
Abbott TDX FLx
Baxter Paramax
Baxter Paramax 720 ZX
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Instrumentation Laboratories IL Monarch Plus
Kodak Ektachem 700 XR

Analyte: Ethosuximide
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Dupont ACA
Dupont ACA IV
Dupont ACA V
Instrumentation Laboratories IL Monarch Plus

Analyte: Flecainide
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx

Analyte: Gentamicin
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Baxter Stratus
Baxter Stratus II
Beckman Array 360
Beckman Synchron CX 4
Beckman Synchron CX 5
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Instrumentation Laboratories IL Monarch Plus
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon Chem 1

Analyte: Kanamycin
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx

Analyte: Lidocaine
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Baxter Stratus
Baxter Stratus II
Dupont ACA
Dupont ACA IV
Dupont ACA V
Instrumentation Laboratories IL Monarch Plus

Analyte: Methadone
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott ADX
Abbott TDX FLx
Instrumentation Laboratories IL Monarch Plus

Analyte: Methamphetamines
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott ADX
Abbott TDX
Abbott TDX FLx

Analyte: Methaqualone
Test Category: Automated procedures that do not require operator

intervention during the analytic process
Test System, Assay or Examination:
Instrumentation Laboratories IL Monarch Plus
Analyte: Methotrexate
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Dupont ACA
Dupont ACA IV
Dupont ACA V
Analyte: N-Acetylprocainamide (NAPA)
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Baxter Stratus
Baxter Stratus II
Dupont ACA
Dupont ACA IV
Dupont ACA V
Instrumentation Laboratories IL Monarch Plus
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Analyte: Netilmycin
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Analyte: Opiates
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott ADX
Abbott TDX
Abbott TDX FLx
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Instrumentation Laboratories IL Monarch Plus
Analyte: Phencyclidine
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott ADX
Abbott TDX
Abbott TDX FLx
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Instrumentation Laboratories IL Monarch Plus
Analyte: Phenobarbital
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Ames Seralyzer
Ames Seralyzer III
Baxter Stratus
Baxter Stratus II
Beckman Array 360
Beckman Synchron CX 4
Beckman Synchron CX 5
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Instrumentation Laboratories IL Monarch Plus
PB Diagnostics OPUS
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon Chem 1
Analyte: Phenytoin
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Ames Seralyzer
Ames Seralyzer III
Baxter Stratus
Baxter Stratus II
Beckman Array 360
Beckman Synchron CX 4
Beckman Synchron CX 5
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Instrumentation Laboratories IL Monarch Plus
PB Diagnostics OPUS
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon Chem 1
Analyte: Phenytoin, Free
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Analyte: Primidone
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Baxter Stratus
Dupont ACA
Dupont ACA IV
Dupont ACA V
Instrumentation Laboratories IL Monarch Plus
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Analyte: Procainamide
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Baxter Stratus
Baxter Stratus II
Dupont ACA
Dupont ACA IV
Dupont ACA V
Instrumentation Laboratories IL Monarch Plus
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Analyte: Propoxyphene
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Instrumentation Laboratories IL Monarch Plus
Analyte: Quinidine
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Baxter Stratus
Baxter Stratus II
Beckman Array 360
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Instrumentation Laboratories IL Monarch Plus
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Analyte: Salicylates
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott ADX

Abbott TDX
Abbott TDX FLx
Baxter Paramax
Baxter Paramax 720 ZX
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Instrumentation Laboratories IL Monarch Plus
Kodak Ektachem 500
Kodak Ektachem 700 XR

Analyte: Streptomycin
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx

Analyte: Theophylline
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Ames Clinimate—TDA
Ames Seralyzer
Ames Seralyzer III
Baxter Stratus
Baxter Stratus II
Beckman Array 360
Beckman Synchron CX 4
Beckman Synchron CX 5
Ciba Corning Biotrack 516
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Instrumentation Laboratories IL Monarch Plus
Kodak Ektachem 500
Kodak Ektachem 700 XR
Kodak Ektachem DT SC Module
PB Diagnostics OPUS
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon Chem 1

Analyte: Tobramycin
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Baxter Stratus
Baxter Stratus II
Beckman Array 360
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Instrumentation Laboratories IL Monarch Plus
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon Chem 1

Analyte: Tricyclic Antidepressants
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott ADX
Abbott TDX
Abbott TDX FLx
Dupont ACA IV
Dupont ACA V

Analyte: Valproic Acid
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Dupont ACA
Dupont ACA IV
Dupont ACA V
Instrumentation Laboratories IL Monarch Plus
PB Diagnostics OPUS
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S

Analyte: Valproic Acid, Free
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx

Analyte: Vancomycin
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Instrumentation Laboratories IL Monarch Plus

Speciality/Subspeciality: Urinalysis
Analyte: Qualitative Urine Dipstick/Tablet Analytes
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Ames Clinitek 100
Ames Clinitek 200 Plus
Behring Rapidmat II
Behring Rapidmat II T

Analyte: Specific Gravity
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Behring Rapidmat II Digital Refractometer

Analyte: Urinary Sediment Microscopic Elements
Test Category: Microscopic analysis of urinary sediment
Test System, Assay or Examination: All Test Systems, Assays or Examinations

Speciality/Subspeciality: Virology
Analyte: Adenovirus
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Analytab Adenovirus Test Kit (EIA) (direct antigen)
Analytab Adenovirus Type 40 & 41 (EIA) (direct antigen)
Cambridge Biotech Adenoclone (EIA) (direct antigen)
Cambridge Biotech Adenoclone-type 40/41 (EIA) (dir Ag)

Analyte: Herpes simplex
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Fairleigh Dickinson Lab ELISA for H. Simplex (dir Ag)
Kodak SureCell (direct antigen)
Wampole Virogen Herpes latex slide test (direct antigen)

Analyte: Respiratory syncitial virus
Test Category: Automated procedures that do not require operator intervention during the analytic process
Test System, Assay or Examination:
Vitek Systems Vidas RSV (direct antigen)

Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Abbott Test Pack RSV (EIA) (direct antigen)
Becton Dickinson Directigen RSV (EIA) (direct antigen)
Sanofi/Kallestad Pathfinder RSV (direct antigen)

Analyte: Respiratory viruses (Influenza A&B, parainfluenza
Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Becton Dickinson Directigen Flu A (direct antigen)

Analyte: Rotavirus

Test Category: Manual procedures with limited steps and limited sample or reagent preparation
Test System, Assay or Examination:
Abbott Rotazyme II Diagnostic Kit (direct antigen)
Analytab API Rotavirus Test Kit (direct antigen)
Bio-Medical ANI Biocard Rotovirus (direct antigen)
Cambridge Biotech Rotaclone (direct antigen)
Isolab RotaVirus EIA (direct antigen)
Medical Technology Corp Rotalex (direct antigen)
Meridian Diag. Meritec Rotavirus Latex (direct antigen)
Sanofi/Kallestad Pathfinder Rotavirus (direct antigen)
V-Tech Target Rotavirus (direct antigen)
Vitek SLIDEX Rota-kit 2 (direct antigen)
Wampole Virogen Rotatest (direct antigen)
Wellcome Rotavirus Latex Test (direct antigen)

Complexity: High

Speciality/Subspeciality: Bacteriology
Analyte: All Organisms
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott MS–2/Advantage
Abbott Quantum II System
Analytab API UniScept System
Baxter AutoSCAN Walk/Away
Baxter MicroScan AutoSCAN 4
Baxter MicroScan Rapid Anaerobe ID Panel
Biolog GN Microplate/ES Microplate
Difco Pasco Tri Panel
Organon Autobac Series II
Radiometer Sensititre
Radiometer Sensititre Gram neg bacteria
Test Category: Identification of aerobes or anaerobes from specimens not in moderate complexity (e.g. Biochem/Physiol)
Test System, Assay or Examination:
Adams Scientific B. Cat Confirm
Adams Scientific Identicult—AE
Adams Scientific Identicult—BL
Adams Scientific Identicult—Neisseria
Adams Scientific Mug-Indole Disc
Adams Scientific Rapid-Hippurate
Adams Scientific Stat-Urease
American Biomedical Prod. B. Fragtex
Anaerobe Systems Bile Differential Disk
Anaerobe Systems Colistin 10 mcg. Differential Disk
Anaerobe Systems Kanamycin 1000 mcg Differential Disk
Anaerobe Systems Vancomycin 5 mcg Differential Disk
Analytab API 20 Streptococcus
Analytab API 20–A
Analytab API An-Ident
Analytab API Laboratories Rapid E
Analytab API Laboratories Rapid NFT
Analytab API Laboratories Rapid Strep
Analytab API StaphTrac
Analytab API Staphase III
Analytab API ZYM Microorganism Differentation
Analytab Quad Ferm +
Baxter Coagulase Plasma
Baxter Haemophilus/Neisseria Identif—Panel
Baxter MicroScan Gram Neg Panels
Baxter MicroScan Gram Pos Panels
Becton Dickinson Cefinase Discs
Becton Dickinson Miniteck
Calbiochem Padac Differentiation Discs
Calbiochem-Behring Anti-Dnase B
Carr Microbiologicals Beta Lactamase Reagent Disc
Carr Microbiologicals CSM Chromogenic B-Lactamase Disc
Carr Microbiologicals Hipp Microtube
Carr Microbiologicals Onpx-Indol Microtube
Carr Microbiologicals PYR Broth
Carr Microbiologicals PYR Discs
Carr Microbiologicals Pgua-Indol Microtube
Carr Microbiologicals Phos Microtubes
Carr Microbiologicals Pro Discs
Carr Microbiologicals Pyrr Microtubes
Carr-Scarborough ALN Differentiation Discs
Carr-Scarborough Acridine Orange Stain
Carr-Scarborough Rapid Glutamic Acid Decarboxy Microtube
Diagnostic Products Corp. PathoDx PYR Kit
Difco Differentiation Discs ALA
Difco Differentiation Discs Colistin 10 mcg
Difco Differentiation Discs Erythromycin 60 mcg
Difco Differentiation Discs Hippurate
Difco Differentiation Discs Kanamycin 1000 mcg
Difco Differentiation Discs Nitrate
Difco Differentiation Discs Penicillin G 2 units
Difco Differentiation Discs Rifampin 15 mcg
Difco Differentiation Discs SPS
Difco Differentiation Discs Spectinomycin
Difco Differentiation Discs Vancomycin 5 mcg
Difco DrySlide Beta-Lactamase
Difco Dryslide Oxidase
Difco Spot Test 10% Na Desoxycholate
Difco Spot Test Acridine Orange Stain
E–Y Laboratories Strep-A-Check PYR
E–Y Laboratories Swabzyme-Oxidase
Innovative Diagnostic Systems Beta Discs
Innovative Diagnostic Systems IDS Rapid SS/U System
Innovative Diagnostic Systems IDS Rapid STR System
Innovative Diagnostic Systems Modified IDS Rapid NH System
Innovative Diagnostic Systems Oxichrome Reagent
Innovative Diagnostic Systems Prophyrin Reagent
Innovative Diagnostic Systems Rap ANA II System
Innovative Diagnostic Systems Rap NF Plus System
Innovative Diagnostic Systems Rapid NF System
Kev Connecticut Diagnostics Visi-Strep
Meridian Indol Spot Test Kit
Micro Media Systems Bacterial ID Panels/Gram Neg/Gram Pos
Micro Media Systems M. Cat. Butyrate Disc
Micro-Bio-Logics KWIK–LAC
Micro-Bio-Logics Lyfo-KWIK OMI Kit
Micro-Bio-Logics Neisseria-KWIK Plus
Microbiological Specialties Beta-ase Tubes
Microbiological Specialties Enzyme-ase I Tubes
Microbiological Specialties Glactosid-ase Tubes
Microtech Medical Systems Quadra-titer ID
Pasco Labs Gram Neg ID System
Pro-Lab Hippurate Test
Pro-Lab Neisseria/Branhamella Differential Test
Pro-Lab Rosco D'Ala Rapid Test
Pro-Lab Rosco Pyrr
Remel ALA Disc
Remel Acridine Orange Stain
Remel Beta Lysin Disc
Remel Beta-Lactam Disc
Remel Bile Disc
Remel CEPH Lactam Disc
Remel Catarrhalis Test Strip
Remel Coagulase Plasma
Remel Colistin Disc
Remel Haemophilus ID Test Kit
Remel Hemastaph
Remel Kanamycin Disc
Remel Legionella ID Disc
Remel Microdase
Remel Nitrate Swab-Rapid Test
Remel Novobiocin Disc
Remel PYR Disc
Remel PYR/Esculin Disc
Remel Prophyrin (ALA) Disc
Remel Pyridoxal Disc
Remel SPS Disc
Remel Urea-PDA Discs

Roche Enterotube II
Unipath Oxoid Bile Esculin Discs
Unipath Oxoid ONPG Discs
Unipath Oxoid Oxidase ID Sticks
Unipath Oxoid SPS Discs
Unipath Oxoid V Factor Discs
Unipath Oxoid X & V Factor Discs
Unipath Oxoid X Factor Discs
Vitek Rapid E System
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Manual antimicrobial susceptibility testing (MIC)
Unipath Oxoid Diagnostic Reagent PET–RPLA
Unipath Oxoid Diagnostic Reagent TST–RPLA
Unipath Oxoid Diagnostic Reagent VET–RPLA
Analyte: Bacterial organisms
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Manual Nucleic Acid analysis
Test Category: Serogrouping or typing
Test System, Assay or Examination:
All Test Systems, Assays or Examinations
Analyte: Chlamydia
Test Category: Antigen or toxin test procedures or kits requiring microscopic evaluations
Test System, Assay or Examination:
Analytab IMAGEN
Baxter Bartels Chlamydiae Fluorescent Monoclonal Antibody
Baxter Bartels Chlamydiae Immunoperoxidase Test Kit
Cellabs Diagnostics Chlamydia-Cel TWAR IFA Test
Diagnostic Products Corp. Chlamydia-Check
Diagnostic Products Corp. PathoDx Chlamydia Trachomatis
Difco Chlamydia Direct Detection System
Incstar Chlamydia Direct Test System
Ortho Chlamydia (DFA)
Ortho Cultureset Chlamydia Identification Kit (FA)
Ortho Cultureset Chlamydia Identification Kit (PAP)
Sanofi/Kallestad Pathfinder (FA)
Scimedx Chlamydia Test Kit
Syva Microtrak Culture confirmation
Syva Microtrak Direct Specimen
Wellcome Chlamysel
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
ADI Diagnostics Visuwell Chlamydia (direct antigen)
Abbott Chlamydiazyme (EIA) (direct antigen)
Baxter Bartels Chlamydia (EIA) (direct antigen)
Ciba Corning Magic Lite Chlamydia (direct antigen)
Ortho Chlamydia Antigen ELISA Test (direct antigen)
Sanofi/Kallestad Pathfinder Chlamydia Microplate (dir. Ag)
Syva Microtrak Chlamydia EIA (direct antigen)
Analyte: Clostridium difficile
Test Category: Antigen or toxin test procedures or kits requiring microscopic evaluations
Test System, Assay or Examination:
Advanced Clinical Diag. CDT Toxi Test
Baxter C. difficile Toxin Assay Kit
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Baxter C. difficile Toxin A (EIA)
Cambridge Biotech Cytoclone A & B (EIA)
Analyte: Legionella
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Binax Equate Legionella Urinary Antigen Kit
Analyte: Legionella pneumophila
Test Category: Antigen or toxin test procedures or kits requiring microscopic evaluations
Test System, Assay or Examination:
Genetic Systems Legionella IFA Test Kit
Litton Legionella/DFA
Medical Diagnostics Technologies Legionella
Scimedx Legionella Test Kit/DFA
Zeus Legionella/DFA & IFA
Analyte: Neisseria gonorrhoeae
Test Category: Antigen or toxin test procedures or kits requiring microscopic evaluations
Test System, Assay or Examination:
Baxter Bartles N. gonorrhoeae Direct Fluorescent
Incstar N.gonorrhaeae Fluoro-Kit
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Abbott Gonozyme (direct antigen)
Analyte: Salmonella
Test Category: Serogrouping or typing
Test System, Assay or Examination:
Analytab API Serum Immsure Salmonella Test Kit
Wellcome Wellcolex Colour Salmonella Test
Analyte: Shigella
Test Category: Serogrouping or typing
Test System, Assay or Examination:
Wellcome Wellcolex Colour Shigella Test
Analyte: Streptococcus, group A
Test Category: Antigen or toxin test procedures or kits requiring microscopic evaluations
Test System, Assay or Examination:
Incstar Group A Streptococcus Fluoro-Kit (DFA test)
Zeus Group A Strep/DFA
Speciality/Subspeciality: General Chemistry
Analyte: ALT (SGPT)
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott Bichromatic ABA 100
Abbott Bichromatic ABA 200
American Monitor KDA
American Monitor Parallel
Technicon SMAC
Analyte: AST (SGOT)
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott Bichromatic ABA 100
Abbott Bichromatic ABA 200
American Monitor KDA
American Monitor Parallel
Technicon SMA 12/60
Technicon SMAC
Analyte: Albumin
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
American Monitor KDA
American Monitor Parallel
Technicon SMA 12/60
Technicon SMAC
Analyte: Alkaline Phosphatase (ALP)
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott Bichromatic ABA 100
Abbott Bichromatic ABA 200
American Monitor KDA
American Monitor Parallel
Analyte: Alpha-Fetoprotein—Maternal Serum
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Abbott AFP EIA
Hybritech Tandem-E
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Amersham Amerlex
Clinical Assays GammaDab
Analyte: Apolipoprotein B
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:

Behring M-partigen Kit
Analyte: Bilirubin, Direct
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
American Monitor KDA
American Monitor Parallel
Technicon SMA 12/60
Technicon SMAC
Analyte: Bilirubin, Total
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
American Monitor KDA
American Monitor Parallel
Technicon SMA 12/60
Technicon SMAC
Analyte: Blood Gases
Test Category: Automated or semi-auto blood gas analyses requiring operator intervention to calibrate instrument, equilibrate gas supplies, introduce sample into measuring chamber or flush sample line
Test System, Assay or Examination:
Ciba Corning 158
Ciba Corning 168
Ciba Corning 170
Ciba Corning 178
Analyte: Blood Lead
Test Category: Anodic stripping voltametry
Test System, Assay or Examination: All Test Systems, Assays or Examinations
Test Category: Atomic absorption
Test System, Assay or Examination: All Test Systems, Assays or Examinations
Analyte: CO2
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
Technicon SMA 6/60
Technicon SMAC
Analyte: Calcium, total
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
American Monitor KDA
American Monitor Parallel
Technicon SMA 12/60
Technicon SMAC
Analyte: Chloride
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
Buchler Chloridometer
Technicon SMA 6/60
Technicon SMAC
Analyte: Chloride, Sweat (Cystic Fibrosis Sweat Test)
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
Advanced Instruments Cystic Fibrosis Analyzer
Analyte: Cholesterol
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
American Monitor KDA
American Monitor Parallel
Technicon SMA 12/60
Technicon SMAC
Analyte: Cortisol
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Amersham Amerlite
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Amersham Amerlex
Becton Dickinson Corti-Cote
Bio-Rad Quantimune
Ciba Corning Magic (MGC)
Clinical Assays GammaCoat
Diagnostic Products Corp. Double Antibody
Micromedic Systems CONCEPT 4
Organon NML
Sanofi/Kallestad Quanticoat
Analyte: Creatine Kinase (CK)
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott Bichromatic ABA 100
Abbott Bichromatic ABA 200
American Monitor KDA
American Monitor Parallel
Technicon SMA 12/60
Technicon SMAC
Analyte: Creatinine
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott Bichromatic ABA 100
Abbott Bichromatic ABA 200
American Monitor KDA
American Monitor Parallel
Technicon SMA 12/60
Technicon SMA 6/60
Technicon SMAC
Analyte: Estradiol
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Amersham Amerlite
Analyte: Estriol-Total
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Amersham Amerlex
Clinical Assays GammaDab
Diagnostic Products Corp. Coat-A-Count
Analyte: Estriol-unconjugated
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Amersham Amerlex
Diagnostic Products Corp. Coat-A-Count
Analyte: Ferritin
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Amersham Amerlite
Hybritech Tandem-E
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Amersham Amerlex
Becton Dickinson MAB
Becton Dickinson Monoclonal Solid Phase Coated Tube
Bio-Rad Quantimune
Diagnostic Products Corp. Coat-A-Count
Hybritech Tandem-R
Nichols Institute Allegro
Ramco IRMA
Analyte: Folate (Folic acid)
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Becton Dickinson Simultrac
Becton Dickinson Simultrac S
Becton Dickinson Simultrac SNB
Bio-Rad Quantphase
Ciba Corning Magic (MGC)
Ciba Corning Magic Boil
Ciba Corning Magic/NB (no boil)
Clinical Assays No Boil
Clinical Assays Solid Phase
Diagnostic Products Corp. Charcoal Boil
Diagnostic Products Corp. Dualcount Charcoal
Diagnostic Products Corp. Dualcount No Boil
Diagnostic Products Corp. Dualcount Solid Phase Boil
Diagnostic Products Corp. Solid Phase/No Boil
Micromedic Combostat II
Analyte: Follicle Stimulating Hormone (FSH)
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Amersham Amerlite
Analyte: Gamma Glutamyl Transferase (GGT)
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process

Test System, Assay or Examination:
American Monitor KDA
American Monitor Parallel
Technicon SMAC
Analyte: Glucose
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott Bichromatic ABA 100
Abbott Bichromatic ABA 200
American Monitor KDA
American Monitor Parallel
Technicon SMA 12/60
Technicon SMA 6/60
Technicon SMAC
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Sclavo
Seradyn
Stanbio
Analyte: Glycosylated Hemoglobin
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Binax Equate Glycohemoglobin
Analyte: HCG, Serum, Quantitative
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Abbott Beta-HCG 15/15
Amersham Amerlite
Diamedix Microassay Test Set
Hybritech Tandem-E
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Amersham Amerlex-M
Becton Dickinson MAB
Becton Dickinson Solid Phase Coated Tube
Bio-Rad Cotube
Ciba Corning Magic (MGC)
Clinical Assays GammaDab
Diagnostic Products Corp. Coat-A-Count
Diagnostic Products Corp. Double Antibody
Hybritech Tandem-R
Nichols Institute Allegro
Organon NML
Serono HCG MAIA Clone
Analyte: HDL Cholesterol (post-precipitation VLDL & LDL)
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott Spectrum
Abbott Spectrum EPX
Abbott Spectrum Series II
Abbott Spectrum Series II CCX
Abbott TDX
Abbott TDX FLx
Abbott VP
Abbott Vision
American Monitor Diagnostics Excel
American Monitor Diagnostics ISP 1000
American Monitor Diagnostics ISP 2000
American Monitor KDA
American Monitor Parallel
Ames Clinistat
Ames Seralyzer III
Baxter Paramax
Baxter Paramax 720 ZX
Beckman Synchron CX 4
Beckman Synchron CX 5
Beckman Synchron CX 7
Boehringer Mannheim Hitachi 704
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 747
Ciba Corning 550 Express
Ciba Corning 570 Alliance
Ciba Corning 580 Alliance
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Analyst
Dupont Dimension
Dupont Dimension AR
Electronucleonics Gem-Profiler
Electronucleonics Gemini
Electronucleonics Gemstar
Electronucleonics Gemstar II
Instrumentation Laboratories IL Monarch
Instrumentation Laboratories IL Monarch Plus
Kodak Ektachem 400
Kodak Ektachem 500
Kodak Ektachem 700
Kodak Ektachem 700 XR
Kodak Ektachem DT 60
Olympus AU 5000
Olympus Demand
Roche Cobas FARA
Roche Cobas FARA II
Roche Cobas Mira
Roche Cobas Mira S
Technicon AXON
Technicon Assist
Technicon Chem 1
Technicon DAX 24
Technicon DAX 48
Technicon DAX 72
Technicon DAX 96
Technicon RA 1000
Technicon RA 2000
Technicon RA 500
Technicon RA XT
Analyte: Insulin
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Ciba Corning Magic (MGC)
Diagnostic Products Corp. Coat-a-Count
Incstar Insulin
Pharmacia Insulin Test
Analyte: Iron
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
American Monitor KDA
American Monitor Parallel
Technicon SMAC
Analyte: Iron Binding Capacity (post saturation/separation)
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott TDX
Abbott TDX FLx
Abbott VP
American Monitor Diagnostics Excel
American Monitor Diagnostics ISP 1000
American Monitor Diagnostics ISP 2000
American Monitor KDA
American Monitor Parallel
Baxter Paramax
Baxter Paramax 720 ZX
Beckman Synchron CX 4
Beckman Synchron CX 5
Beckman Synchron CX 7
Boehringer Mannheim Hitachi 704
Boehringer Mannheim Hitachi 705
Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 747
Dupont ACA
Dupont ACA IV
Dupont ACA V
Dupont Dimension
Dupont Dimension AR
Electronucleonics Gem-Profiler
Electronucleonics Gemini
Electronucleonics Gemstar
Electronucleonics Gemstar II
Instrumentation Laboratories IL Monarch
Instrumentation Laboratories IL Monarch Plus
Kodak Ektachem 400
Kodak Ektachem 500
Kodak Ektachem 700
Kodak Ektachem 700 XR
Olympus AU 5000
Olympus Demand
Technicon Assist
Technicon Chem 1
Technicon RA 1000
Technicon RA 500
Analyte: Lactate Dehydrogenase (LDH)
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott Bichromatic ABA 100
Abbott Bichromatic ABA 200

American Monitor KDA
American Monitor Parallel
Technicon SMA 12/60
Technicon SMAC
Analyte: Lithium
Test Category: Atomic absorption
Test System, Assay or Examination:
Instrumentation Laboratories AA Spectro
Perkin Elmer
Test Category: Flame photometry
Test System, Assay or Examination:
Beckman Flame Photometer
Ciba Corning Flame Photometer
Instrumentation Laboratories IL Flame Photometer/Elect
Radiometer Flame Photometer
Analyte: Luteinizing Hormone (LH)
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Amersham Amerlite
NMS Pharmaceuticals COT Ovulation Test
Analyte: Magnesium
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
American Monitor KDA
American Monitor Parallel
Analyte: Phosphorus
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
American Monitor KDA
American Monitor Parallel
Technicon SMA 12/60
Technicon SMAC
Analyte: Potassium
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
Technicon SMA 6/60
Technicon SMAC
Test Category: Flame photometry
Test System, Assay or Examination:
Beckman Flame Photometer
Instrumentation Laboratories IL Flame Photometer/Elect
Radiometer Flame Photometer
Analyte: Progesterone
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Amersham Amerlite
Analyte: Prolactin
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Amersham Amerlite
Hybritech Tandem-E
Analyte: Prostatic Acid Phosphatase
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Abbott PAP EIA
Hybritech Tandem-E
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Clinical Assays GammaDab
Dupont RIANEN
Hybritech Tandem-R
Yang Laboratories RIA
Analyte: Protein, Total
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
Technicon SMA 12/60
Technicon SMAC
Analyte: Retinol binding protein
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Behring LC-partigen Kit
Analyte: Sodium
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
Technicon SMA 6/60
Technicon SMAC
Test Category: Flame photometry
Test System, Assay or Examination:
Beckman Flame Photometer
Instrumentation Laboratories IL Flame Photometer/Elect
Radiometer Flame Photometer
Analyte: Thyroid Stimulating Hormone (TSH)
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Amersham Amerlite
Ciba Corning Magic Lite
Diamedix Microassay Test Set
Hybritech Tandem-E
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Abbott RIA Bead
Becton Dickinson MAB
Bio-Rad Cotube
Bio-Rad Echoclonal
Ciba Corning MAB (monoclonal)
Ciba Corning Magic (MGC)
Clinical Assays GammaDab
Diagnostic Products Corp. Coat-A-Count
Hybritech Tandem-R
Nichols Institute Allegro
Organon NML
Organon NML L.E.S.
Sanofi/Kallestad Quanticlone
Serono Maiaclone
Ventrex
Analyte: Thyroid Stimulating Hormone (TSH) (Neonatal)
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Diagnostic Products Corp. Double Antibody
Analyte: Thyroid Stimulating Hormone—high sens. (TSH–HS)
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Hybritech Tandem-E
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Clinical Assays GammaCoat
Hybritech Tandem-R
Analyte: Thyroxine (T4)
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Amersham Amerlite
Diamedix Microassay Test Set
Syva Emit
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Becton Dickinson Monoclonal Solid Phase Coated Tube
Ciba Corning Magic (MGC)
Clinical Assays GammaCoat
Diagnostic Products Corp. Coat-a-Count
Micromedic Systems CONCEPT 4
Organon NML Tetra Tab
Organon NML Tetra Tube
Sanofi/Kallestad Quanticoat
Ventrex Coated Tube
Analyte: Thyroxine, Free (FT–4)
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Amersham Amerlite
Ciba Corning Magic Lite
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Amersham Amerlex-M
Becton Dickinson MAB
Becton Dickinson Simultrac
Becton Dickinson Solid Phase Coated Tube
Ciba Corning Magic (MGC)
Clinical Assays Direct FT4
Clinical Assays Two Step
Diagnostic Products Corp. Coat-a-Count
Analyte: Triglyceride
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
American Monitor KDA
American Monitor Parallel
Technicon SMA 12/60
Technicon SMAC
Analyte: Triiodothyronine (T–3) Uptake

Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Amersham Amerlite
Ciba Corning Magic Lite
Diamedix Microassay Test Set
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Abbott Triobead 125
Becton Dickinson Solid Phase
Ciba Corning Magic (MGC) (25–35 normal range)
Ciba Corning Magic (MGC) (35–45 normal range)
Clinical Assays GammaCoat
Diagnostic Products Corp. Coat-a-Count
Microgenics
Micromedic Systems CONCEPT
Organon NML Tri Tab
Organon NML Tri Tube T3U
Sanofi/Kallestad Quanticoat
Analyte: Triiodothyronine (T3)
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Amersham Amerlite
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Abbott RIA Bead
Amersham Amerlex-M
Becton Dickinson Solid Phase
Bio-Rad Quantimune II
Ciba Corning Magic (MGC)
Clinical Assays GammaCoat
Diagnostic Products Corp. Coat-A-Count
Diagnostic Products Corp. Double Antibody
Micromedic Systems CONCEPT 4
Organon NML
Sanofi/Kallestad Quanticoat
Analyte: Triiodothyronine, Free (FT–3)
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Amersham Amerlite
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Amersham Amerlex-M
Diagnostic Products Corp. Coat-a-Count
Analyte: Urea (BUN)
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
Abbott Bichromatic ABA 100
Abbott Bichromatic ABA 200
American Monitor KDA
American Monitor Parallel
Technicon SMA 12/60
Technicon SMA 6/60
Technicon SMAC
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Seradyn
Analyte: Uric Acid
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
American Monitor KDA
American Monitor Parallel
Technicon SMAC
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Seradyn
Analyte: Vitamin B12
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Becton Dickinson Simultrac
Becton Dickinson Simultrac S
Becton Dickinson Simultrac SNB
Bio-Rad Quantphase
Ciba Corning Magic (MGC)
Ciba Corning Magic Boil
Ciba Corning Magic/NB (no boil)
Clinical Assays No-Boil
Clinical Assays Solid Phase
Diagnostic Products Corp. Charcoal Boil
Diagnostic Products Corp. Dualcount Charcoal
Diagnostic Products Corp. Dualcount No Boil
Diagnostic Products Corp. Dualcount Solid Phase Boil
Diagnostic Products Corp. Solid Phase/N Boil
Micromedic Combostat II
Speciality/Subspeciality: General Immunology
Analyte: Adenovirus Antibodies
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Virotech ELISA Antibody Test
Analyte: Albumin
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Behring LC-partigen Kit
Behring Nor-partigen Kit
Kallestad Endoplate RID
Kallestad Quantiplate RID
Analyte: Allergen specific IgE
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
3M Allergen Specific IgE FAST-Plus Test
3M IgE FASTSCREEN Assay
Alercheck Flipscreen II Visual Allergy Test
Alercheck Flipscreen quantitative Allergy Tests
Diagnostic Products Corp. AlaSTAT
MAST Allergy Systems (chemiluminescence)
Analyte: Allergen specific IgG
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination: 3M Allergen Specific IgG4 FAST Test
Analyte: Alpha-1-Acid Glycoprotein (orosomucoid)
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Behring Nor-partigen Kit
Hycor Accuplate
Kent Radial Immunodiffusion Test
Analyte: Alpha-1-Antitrypsin
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Behring Nor-partigen Kit
Helena Laboratories Quiplate System for RID
Hycor Accuplate
Kallestad Endoplate RID
Kallestad Quantiplate RID
Kent Radial Immunodiffusion Test
Analyte: Alpha-2-Macroglobulin
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Behring Nor-partigen Kit
Kent Radial Immunodiffusion Test
Analyte: Alpha-Fetoprotein—Tumor Marker
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Hybritech Tandem-E
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Amersham Amerlex
Clinical Assays GammaDab
Analyte: Anti-Adrenal Antibodies
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
Scimedx Anti-adrenal Test System
Analyte: Anti-Brush Border Antibodies
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
Incstar Fluoro-Kit
Analyte: Anti-Canalicular Antibodies
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
Incstar Fluoro-Kit
Analyte: Anti-Cardiac Muscle Antibodies
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
Scimedx CMA Test System
Analyte: Anti-Cardiolipin Antibodies

Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
BioHyTech EIA Kit
Reaads Medical Products Anti-cardiolipin Semi-quant. Test
Sanofi/Kallestad Anti-cardiolipin Kit (EIA)
TheraTest Laboratories EL-ACA Test
Analyte: Anti-DNA Antibodies
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
Antibodies Inc. CrithiDNA Test Kit
Behring AFT System II
Incstar nDNA Fluoro-Kit
MarDx Anti-nDNA Antibody Test System
MeDiCa A-nDNA-A Test Kit
MeDiCa ANA/A-nDNA-A Test Kit
MeDiCa Multiple Antibody Test Kit
Sanofi/Kallestad Quantifluor Kit
Scimedx nDNA Test System
Virgo Anti-nDNA IFA Test
Zeus Anti-DNA Test System
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
BioHyTech EIA Kit
Diamedix Microassay Test Set
Hemagen DNA
Reaads Medical Products Anti-ds DNA Semi-quantitative Test
Sigma EIA
TheraTest Laboratories EL-ANA Profiles Test
Whittaker Bioproducts FIAX System
Whittaker Bioproducts RheumELISA kit
Whittaker Bioproducts dsDNA STAT
Analyte: Anti-DNP antibodies
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
BioHyTech EIA Kit
Diamedix Microassay Test Set
Sigma EIA
Analyte: Anti-Histone Antibodies
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
BioHyTech EIA Kit
Analyte: Anti-Jo-1
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Hemagen ENA
Analyte: Anti-Mitochondrial Antibodies (AMTA)
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
Behring AFT System I
Incstar Fluoro-Kit
MarDx Autoimmune IFA Screening Test System
MarDx Mitochondrial Antibodies Test System
MeDiCa AMA Test Kit
MeDiCa Multiple Antibody Test Kit
Sanofi/Kallestad Quantifluor Kit
Scimedx Auto Screen Test System
Scimedx MA Test System
Virgo AMA IFA Test
Zeus MA Test System
Analyte: Anti-Neutrophil Cytoplasm Antibodies
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
Scimedx Anti-Neutrophil Cytoplasm Antibody IFA Test System
Analyte: Anti-Nuclear Antibodies (ANA)
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
Amico ANA Test System
Antibodies Inc.
Behring AFT System I
Bion ANA Test Kit
Clinical Sciences
Hemagen
INOVA Diagnostics, Inc.
Immuno Concepts
Incstar ANA Colorimetric Kit
Incstar ANAFAST Kit
Incstar ANAFLUOR Kit
Incstar ANAZYME Kit
Incstar RL Fluoro-Kit ANA Fluorescent test
MarDx ANA Test System
MarDx Autoimmune IFA Screening Test System
MeDiCa ANA Test Kit
MeDiCa ANA/A-nDNA-A Test Kit
MeDiCa Multiple Antibody Test Kit
Ortho Fluoroset ANA
Quidel ANA IFA kit
Sanofi/Kallestad Quantifluor Kit
Scimedx ANA Test System
Scimedx Auto Screen Test System
Virgo ANA IFA Test
Zeus ANA Test
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
BioHyTech EIA Kit
Whittaker Bioproducts FIAX System
Analyte: Anti-Parietal Cell Antibodies
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
Incstar Fluoro-Kit
MarDx Autoimmune IFA Screening Test System
MarDx Parietal Cell Antibody Test System
MeDiCa APCA Test Kit
MeDiCa Multiple Antibody Test Kit
Sanofi/Kallestad Quantifluor Kit
Scimedx Auto Screen Test System
Scimedx PCA Test System
Analyte: Anti-RNP (Ribonucleoprotein)
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Behring ENA I Test
Scimedx ENA Detect I Test System
Scimedx ENA Detect II Test System
Scimedx ENA Detect III Test System
Zeus Poly-ENA Assay
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
BioHyTech EIA Kit
Diamedix Microassay Test Set
General Biometrics ImmunoWELL Sm/RNP Antibody Test
Hemagen ENA
Reaads Medical Products Anti-ENA (Sm/RNP complex) Qual Test
TheraTest Laboratories EL–ANA Profiles Test
Whittaker Bioproducts RheumELISA kit
Analyte: Anti-Reticulin Antibodies
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
Incstar Fluoro-Kit
Scimedx Auto Screen Test System
Analyte: Anti-Ribosomal Antibodies
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
Incstar Fluoro-Kit
Analyte: Anti-SS-A/Ro
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Behring ENA II Test
Scimedx ENA Detect III Test System
Zeus Poly-ENA Assay
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Diamedix Microassay Test Set
General Biometrics ImmunoWELL SS-A (Ro) Antibody Test
Hemagen ENA
TheraTest Laboratories EL-ANA Profiles Test
Whittaker Bioproducts RheumELISA kit
Analyte: Anti-SS-B/La
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Behring ENA II Test
Scimedx ENA Detect II Test System
Scimedx ENA Detect III Test System
Zeus Poly-ENA Assay
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Diamedix Microassay Test Set

General Biometrics ImmunoWELL SS-B (La) Antibody Test
Hemagen ENA
TheraTest Laboratories EL-ANA Profiles Test
Whittaker Bioproducts RheumELISA kit
Analyte: Anti-Scl-70
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Behring ENA III Test
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Diamedix Microassay Test Set
Hemagen ENA
Analyte: Anti-Skin Antibodies
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
MarDx Anti-Skin Antibody Test System
MeDiCa ASA Test Kit
Scimedx ASA Test System
Zeus Anti-Skin Antibody Test System
Analyte: Anti-Sm (Smith)
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Behring ENA I Test
Scimedx ENA Detect I Test System
Scimedx ENA Detect II Test System
Scimedx ENA Detect III Test System
Zeus Poly-ENA Assay
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
BioHyTech EIA Kit
Diamedix Microassay Test Set
General Biometrics ImmunoWELL Sm Antibody Test
Hemagen ENA
Reaads Medical Products Anti-ENA (Sm/RNP complex) Qual Test
Reaads Medical Products Anti-SM Qualitative Test
TheraTest Laboratories EL-ANA Profiles Test
Whittaker Bioproducts RheumELISA kit
Analyte: Anti-Smooth Muscle Antibodies (ASMA)
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
Behring AFT System I
Incstar Fluoro-Kit
MarDx Autoimmune IFA Screening Test System
MarDx Smooth Muscle Antibody Test System
MeDiCa ASMA Test Kit
MeDiCa Multiple Antibody Test Kit
Sanofi/Kallestad Quantifluor Kit
Scimedx SMA Test System
Zeus SMA Test System
Analyte: Anti-Thyroglobulin Antibodies (ATA)
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Ames Sera-tek
General Biometrics Thyroglobulin Antibody Test
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Kronus Kalibre-R Thyroglobulin Antibody RIA Kit
Analyte: Anti-Thyroid Antibodies
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
Incstar MT Fluoro-Kit
MarDx Anti-Thyroid Antibody Test System
MeDiCa ATA Test Kit
Sanofi/Kallestad Quantifluor Kit
Scimedx TA Test System
Zeus TA Test System
Analyte: Anti-Thyroid Microsomal Antibodies (AMA)
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Ames Sera-tek
General Biometrics Microsomal(Recombinant TPO) Ab Test
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Kronus Kalibre TPO Antibody RIA Kit
Analyte: Bordetella pertussis Antibodies
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Labsystems Bordetella pertussis IgG EIA Kit
Analyte: C-Reactive Protein (CRP)
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Behring LC-partigen Kit
Hycor Accuplate
Kent Radial Immunodiffusion Test
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Whittaker Bioproducts FIAX System
Analyte: Candida albicans Antibodies
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Immuno-Mycologics ID-Candida Antibody System
Meridian Diagnostics Candida Immunodiffusion System
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Immuno-Mycologics Candi-Sphere EIA (CEIA)
Analyte: Carcinoembryonic Antigen (CEA)
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Abbott CEA-EIA Monoclonal
Abbott CEA-EIA One-Step
Hybritech Tandem-E
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Abbott RIA Monoclonal
Hybritech Tandem-R
Analyte: Ceruloplasmin
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Behring Nor-partigen Kit
Kent Radial Immunodiffusion Test
Analyte: Chlamydia Trachomatis Antibodies
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
Amico Amizyme Chlamydia Trachomatis Antibody Test
Incstar Fluoro-Kit
Virgo Chlamydia trachomatis IFA Test
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Whittaker Bioproducts CHLAMYDELISA II
Whittaker Bioproducts CHLAMYDIA STAT
Analyte: Coccidioides Antibodies
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Immuno-Mycologics ID-Cocci Antibody System
Analyte: Complement C1 inhibitor
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Kent Radial Immunodiffusion Test
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Quidel C1–Inhibitor EIA
Analyte: Complement C1q
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Kent Radial Immunodiffusion Test
Analyte: Complement C2
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Kent Radial Immunodiffusion Test
Analyte: Complement C3

Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Behring Nor-partigen Kit
Helena Laboratories Quiplate System for RID
Hycor Accuplate
Kallestad Endoplate RID
Kallestad Quantiplate RID
Kent Radial Immunodiffusion Test
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Whittaker Bioproducts FIAX System
Analyte: Complement C4
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Behring Nor-partigen Kit
Helena Laboratories Quiplate System for RID
Hycor Accuplate
Kallestad Endoplate RID
Kallestad Quantiplate RID
Kent Radial Immunodiffusion Test
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Whittaker Bioproducts FIAX System
Analyte: Complement C5
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Kent Radial Immunodiffusion Test
Analyte: Cytomegalovirus Antibodies (IgG/IgM)
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
Amico Amizyme CMV Ab Test
Bion CMV-G Antibody Test System
Gull Laboratories CMV IgM Test
Gull Laboratories CMV Test
Incstar Fluoro-Kit
Virgo Cytomegalovirus IFA Test
Zeus CMV Test System
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Abbott CMV Total AB EIA
Diamedix Microassay Test Set
Gull Laboratories CMV IgG ELISA
Gull Laboratories CMV IgM ELISA
Immucor Capture CMV
Incstar Clin-ELISA Test System
Labsystems CMV IgG EIA Kit
Labsystems CMV IgM EIA Kit
Sigma EIA
Virotech ELISA Antibody Test
Whittaker Bioproducts CMV CAP-M
Whittaker Bioproducts CMV STAT
Whittaker Bioproducts CMV STAT M
Whittaker Bioproducts CYTOMEGELISA II
Whittaker Bioproducts FIAX System
Zeus CMV IgG ELISA
Analyte: Entamebia histolytica Antibodies
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Sigma EIA
Analyte: Epstein-Barr virus Antibodies
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
Amico Amizyme EBV Ab Test
Bion EBV–G (VCA) Antibody Test System
Bion EBV–M (VCA) Antibody Test System
Diagnostic Technology EBNA Check
Diagnostic Technology EBV Check
Diagnostic Technology EBV/EA Check
Diagnostic Technology EBV/IgM Check
Granbio Inc. EBNA Anti-complement IFA
Granbio Inc. Epstein-Barr EA IgG IFA
Granbio Inc. Epstein-Barr VCA IgG IFA
Granbio Inc. Epstein-Barr VCA IgM IFA
Gull Laboratories EBV IgM Test
Gull Laboratories EBV Test
Gull Laboratories EBV–EA Test
Gull Laboratories EBV–NA Test
Organon Teknika EB–VCA IFA Kit II
Organon Teknika EBNA ACIF Kit
Organon Teknika EBV–EA IFA Kit
Organon Teknika EBV–M Kit
Virgo Epstein-Barr Virus—VCA Antibody IFA Test
Zeus EBV–EA Test System
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Granbio Inc. Epstein-Barr VCA IgG EIA
Granbio Inc. Epstein-Barr VCA IgM EIA
Gull Laboratories EBV IgG ELISA
Gull Laboratories EBV IgM ELISA
Incstar Clin-ELISA Test System
Ortho EBNA IgG Antibody ELISA
Ortho Epstein-Barr Virus VCA–IgG Antibody ELISA
Ortho Epstein-Barr Virus VCA–IgM Antibody ELISA
Whittaker Bioproducts EB VCA STAT
Whittaker Bioproducts EB VCA STAT M
Whittaker Bioproducts EBNA STAT
Whittaker Bioproducts FIAX System
Analyte: Febrile Agglutinins
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Becton Dickinson BBL—Tube Test
Difco Bacto-Tube Test
Gamma Biologicals Tube Test
Analyte: Fungus Antibodies
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Immuno-Mycologics ID–Fungal Antibody System
Meridian Diagnostics Fungal Immunodiffusion System
Analyte: HIV Antibody
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Abbott HIVAB HIV–1 EIA
Cambridge Biotech Recombigen (env. & gag) HIV–1 EIA
Cellular Products Retro-Tek HIV–1 ELISA
Dupont HIV–1 ELISA
Electronucleonics HIV–1 IgG EIA
Genetic Systems HIV–1/HIV–2 EIA
Genetic Systems HIV–2 EIA
Genetic Systems LAV EIA
Organon Teknika Bioenzabead HIV
Organon Teknika Vironostilca HIV
Ortho Diagnostics HIV–1 ELISA
Syva Microtrak HIV–1 (env & gag) EIA
United Biomedical HIV–1 EIA
Test Category: Western blot
Test System, Assay or Examination:
Bio-Rad Novapathe HIV–1 Immunoblot
Cambridge Biotech HIV–1 WB
Organon Teknika Epiblot HIV
Analyte: HIV Antigen
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Abbott HIVAG–1
Analyte: HTLV Antibody
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Abbott HTLV–1 EIA
Cellular Products Retro-Tek HTLV–1 ELISA
Dupont HTLV–1 ELISA
Analyte: Haptoglobin
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Behring Nor-partigen Kit
Hycor Accuplate
Kallestad Endoplate RID
Kallestad Quantiplate RID
Kent Radial Immunodiffusion Test
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Whittaker Bioproducts FIAX System
Analyte: Helicobacter pylori Antibodies

Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Whittaker Bioproducts FIAX System
Whittaker Bioproducts PYLORI STAT
Analyte: Hemopexin
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Behring Nor-partigen Kit
Analyte: Hepatitis A Antibody (HAVAb)
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Abbott HAVAB EIA
Organon Teknika Hepanostika Anti-HAV Microelisa System
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Abbott HAVAB
Sorin Biomedica AB–HAVK
Analyte: Hepatitis A Antibody—IgM
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
ADI Diagnostics Anti-HAV IgM EIA (Heprofile)
Abbott HAVAB–M EIA
Organon Teknika Hepanostika Anti-HAV IgM Microelisa System
Sorin Biomedica ETI–HA–IgMK
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Abbott HAVAB–M RIA
Sorin Biomedica HA–IgMK (IRMA)
Analyte: Hepatitis B Core Antibody (Hb Core)
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Abbott CORZYME
Genetic Systems Anti-HBc EIA
Organon Teknika Hepanostika ANTICORE Microelisa System
Ortho HBc ELISA
Sorin Biomedica ETI–AB–COREK (EIA)
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Abbott CORAB
Sorin Biomedica AB–COREK, AB–COREK J
Analyte: Hepatitis B Core Antibody—IgM
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Abbott CORZYME–M
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Abbott CORAB–M
Sorin Biomedica CORE–IgMK (IRMA)
Analyte: Hepatitis B Surface Antibody
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Abbott AUSAB Quantitation Panel
Abbott AUSAB–EIA
Organon Teknika Microplate Anti-HBs EIA
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Abbott AUSAB
Abbott AUSAB Quantitation Panel
Sorin Biomedica AB–AUK–3 (RIA)
Analyte: Hepatitis B Surface Antigen (HBS Ag)
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Abbott AUSCELL (RPHA)
Abbott AUSCELL Confirmatory Test (RPHA)
Abbott AUSZYME (EIA)
Abbott AUSZYME Confirmatory Test
Genetic Systems HBsAg Confirmatory Test
Genetic Systems HBsAg EIA
Organon NML ELISA HBsAg Confirmatory Test
Organon NML ELISA HBsAg Screening Test
Ortho Antibody to HBsAg ELISA Confirmatory Test
Ortho Antibody to HBsAg ELISA Test System II
Pharmacia Hepatitis B Surface Antigen Confirmatory Test
Pharmacia Hepatitis B Surface Antigen-AntiHBs ELISA
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Abbott AUSRIA
Organon NML RIA HBsAg Confirmatory Test
Organon NML RIA HBsAg Screening Test
Sorin Biomedica AUK–3, AUK 3J (RIA)
Sorin Biomedica Confirmatory Test
Analyte: Hepatitis Be Antibody
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Abbott HBe (rDNA) EIA
Organon Teknika Hepanostika HBeAg/Anti-HBe Microelisa
Sorin Biomedica ETI–EBK (EIA)
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Abbott HBe
Sorin Biomedica EBK (RIA)
Analyte: Hepatitis Be Antigen
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Abbott HBe (rDNA) EIA
Organon Teknika Hepanostika HBeAg/Anti-HBe Microelisa
Sorin Biomedica ETI–EBK (EIA)
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Abbott HBe RIA
Sorin Biomedica EBK (RIA)
Analyte: Hepatitis C Virus Antibody
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Abbott HCV–EIA
Ortho HCV ELISA
Analyte: Hepatitis delta Antibody
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Abbott Anti-delta-EIA
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Abbott Anti-delta
Analyte: Herpes simplex I and/or II Antibodies
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
Amico Amizyme HSV Ab Test
Bion HSV1–G or HSV2–G Test System
Diagnostic Technology HSV Check
Gull Laboratories HSV IgM Test
Gull Laboratories HSV Test
Incstar Fluoro-Kit
Ortho Herpes simplex virus Antibodies Fluoroset
Virgo Herpes Simplex Virus Type 1 Antibody IFA Test
Virgo Herpes Simplex Virus Type 2 Antibody IFA Test
Zeus HSV Antibody Test System
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Diamedix Microassay Test Set
Gull Laboratories HSV–1 IgG ELISA
Gull Laboratories HSV–1 IgM ELISA
Gull Laboratories HSV–2 IgG ELISA
Gull Laboratories HSV–2 IgM ELISA
Incstar Clin-ELISA Test System
Sigma EIA
Whittaker Bioproducts FIAX System
Whittaker Bioproducts HERPELISA II
Whittaker Bioproducts HERPES 1&2 STAT
Whittaker Bioproducts HERPES STAT
Zeus HSV–1 and HSV–2 ELISA
Analyte: Histoplasma Antibodies
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Immuno-Mycologics ID-Histo Antibody System
Analyte: Immune complexes (CIC)
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:

Diamedix Microassay Test Set
Quidel CIC-C1q EIA
Quidel CIC-Raji Cell Replacement EIA
Sigma EIA
Analyte: Immunoglobulins—monoclonal/polyclonal
Test Category: Electrophoresis
Test System, Assay or Examination:
Helena Laboratories Titan Gel ImmunoFix
Helena Laboratories Titan Gel Immunoelectrophoresis
Kallestad Immunoelectrophoresis System
Analyte: Immunoglobulins IgA
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Behring LC-partigen Kit
Behring Nor-partigen Kit
Helena Laboratories Quiplate System for RID
Hycor Accuplate
Kallestad Endoplate RID
Kallestad Quantiplate RID
Kent Radial Immunodiffusion Test
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Whittaker Bioproducts FIAX System
Analyte: Immunoglobulins IgD
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Helena Laboratories Quiplate System for RID
Hycor Accuplate
Kallestad Endoplate RID
Kallestad Quantiplate RID
Kent Radial Immunodiffusion Test
Analyte: Immunoglobulins IgE
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
3M Total IgE II FAST Test
Alercheck Flipscreen Total IgE
Diagnostic Products Corp. AlaSTAT Total IgE
Nichols Institute Allegro IgE
Whittaker Bioproducts FIAX System
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Leeco Diagnostics IgE Quant
Analyte: Immunoglobulins IgG
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Behring LC-partigen Kit
Behring Nor-partigen Kit
Helena Laboratories Quiplate System for RID
Hycor Accuplate
Kallestad Endoplate RID
Kallestad Quantiplate RID
Kent Radial Immunodiffusion Test
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Whittaker Bioproducts FIAX System
Analyte: Immunoglobulins IgG subclasses
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Janssen Biochimica IgG subclasses ELISA Kit
Analyte: Immunoglobulins IgM
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Behring LC-partigen Kit
Behring Nor-partigen Kit
Helena Laboratories Quiplate System for RID
Hycor Accuplate
Kallestad Endoplate RID
Kallestad Quantiplate RID
Kent Radial Immunodiffusion Test
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Whittaker Bioproducts FIAX System
Analyte: Influenza A Antibodies
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Virotech ELISA Antibody Test
Analyte: Influenza B Antibodies
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Virotech ELISA Antibody Test
Analyte: Legionella Antibodies
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
MarDx Legionella IFA Test System
Organon Teknika Legionella IFA Kit I
Scimedx Lyme Detect Test System
Zeus Legionella IFA
Analyte: Lyme Disease Antibodies (Borrelia burgdorferi Abs
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
MarDx Lyme Disease IgG IFA Test System
MarDx Lyme Disease IgM IFA Test System
Scimedx Lyme Detect Test System
Zeus Lyme Disease Antibody Test System
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
3M IgG/IgM FASTLYME Test
Cambridge Biotech Human Lyme EIA
Diamedix Microassay Test Set
General Biometrics Borrelia (Lyme) Test
General Biometrics Recombinant P39 (Lyme) Test
Gull Laboratories Lyme IgM ELISA
MarDx Lyme Disease EIA (IgM & IgG)
MarDx Lyme Disease EIA IgG
MarDx Lyme Disease EIA IgM
Sigma EIA
Whittaker Bioproducts FIAX System
Whittaker Bioproducts LYME STAT
Whittaker Bioproducts LYME STAT M
Zeus Lyme ELISA
Zeus Lyme IgG ELISA
Zeus Lyme IgM ELISA
Analyte: Mumps Antibodies
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
Virgo Mumps Antibody IFA Test
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Whittaker Bioproducts FIAX System
Whittaker Bioproducts MUMPSTAT
Analyte: Mycoplasma pneumonia Antibodies
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
Zeus MP IgM Test System
Zeus MP Test System
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Incstar IgM–MP Reverse ELISA Kit
Incstar Mp Test IgM/IgG MA Reverse ELISA Kit
Seradyn Color Vue
Whittaker Bioproducts FIAX System
Whittaker Bioproducts MYCOPLASMA STAT
Whittaker Bioproducts MYCOPLASMELISA II
Analyte: Plasminogen
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Helena Laboratories Quiplate System for RID
Analyte: Prealbumin
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Behring M-partigen Kit
Kent Radial Immunodiffusion Test
Analyte: Properdin Factor B
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Kent Radial Immunodiffusion Test
Analyte: Prostatic Specific Antigen (PSA)

Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Hybritech Tandem-E
Analyte: Protein Fractions
Test Category: Electrophoresis
Test System, Assay or Examination:
Helena Laboratories Super Z Serum Protein Kit
Helena Laboratories Titan Gel High Resolution Protein Kit
Analyte: Respiratory syncitial virus Antibodies
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
Gull Laboratories RSV Test
Virgo RSV Antibody IFA Test
Analyte: Rheumatoid Factor (RA)
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Alercheck RF Assay
Diamedix Microassay Test Set
Hemagen RF
Sigma EIA
Whittaker Bioproducts FIAX System
Analyte: Rubella Antibodies, IgG/IgM
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
Virgo Rubella Antibody IFA Test
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Abbott Rubazyme
Abbott Rubazyme-M
Diamedix Microassay Test Set
Gull Laboratories Rubella IgG ELISA
Gull Laboratories Rubella IgM ELISA
Incstar Clin-ELISA Test System
Labsystems Rubella IgM EIA Kit
Sigma EIA
Whittaker Bioproducts FIAX System
Whittaker Bioproducts RUBECAP–M
Whittaker Bioproducts RUBELISA II
Whittaker Bioproducts RUBESTAT
Whittaker Bioproducts RUBESTAT M
Zeus Rubella IgG ELISA
Analyte: Rubeola Antibodies (measles)
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
Bion Measles-G Antibody Test System
Bion Measles-M Antibody Test System
Gull Laboratories Rubeola Test
Virgo Measles Antibody IFA Test
Zeus Measles Test System
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Diamedix Microassay Test Set
Gull Laboratories Rubeola IgG ELISA
Gull Laboratories Rubeola IgM ELISA
Incstar Clin-ELISA Test System
Virotech ELISA Antibody Test
Whittaker Bioproducts FIAX System
Whittaker Bioproducts MEASELESTAT
Whittaker Bioproducts MEASELESTAT M
Whittaker Bioproducts MEASELISA II
Analyte: Schistosoma Antibodies
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
Amico Amizyme Schistosoma species Ab Test System
Analyte: TSH Receptor Antibody
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Kronus Kalibre-R TSH Receptor (TRAb) Kit
Analyte: Tetanus toxoid Antibodies
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Labsystems Tetanus Toxoid EIA Test Kit
Analyte: Toxoplasma gondii Antibodies (IgG/IgM)
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
Amico Amizyme Toxoplasma gondii Ab Test System
Diagnostic Technology Toxo/IgM Check
Gull Laboratories Toxo IgM Test
Gull Laboratories Toxo Test
Incstar Fluoro-Kit
Organon Teknika Toxo IFA Kit I
Virgo Toxoplasma gondii Antibody IFA Test
Zeus IFA Toxoplasma Test System
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Abbott Toxo-G EIA Kit
Abbott Toxo-M EIA Kit
Diamedix Microassay Test Set
Gull Laboratories Toxo IgG ELISA
Gull Laboratories Toxo IgM ELISA
Incstar Clin-ELISA Test System
Labsystems Toxoplasma gondii IgG EIA Kit
Sigma EIA
Whittaker Bioproducts FIAX System
Whittaker Bioproducts TOXOCAP–M
Whittaker Bioproducts TOXOELISA II
Whittaker Bioproducts TOXOSTAT
Whittaker Bioproducts TOXOSTAT M
Zeus TOXO ELISA IgG
Zeus TOXO IgM ELISA
Analyte: Transferrin
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Behring Nor-partigen Kit
Helena Laboratories Quiplate System for RID
Hycor Accuplate
Kallestad Endoplate RID
Kallestad Quantiplate RID
Kent Radial Immunodiffusion Test
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Whittaker Bioproducts FIAX System
Analyte: Treponema pallidum Antibodies
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
Incstar Fluoro-Kits (FTA-ABS)
MarDx FTA-ABS Test System
Scimedx FTA-ABS Test System
Virgo FTA-ABS IFA Test
Zeus FTA-ABS Test System
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
ADI Diagnostics Visuwell Reagin
Difco Bacto VDRL
Fisher Diagnostic VDRL
Analyte: Varicella-Zoster Virus Antibodies
Test Category: Immunoassay methods requiring microscopic evaluations
Test System, Assay or Examination:
Gull Laboratories VZV Test
Virgo Varicella-zoster Antibody IFA Test
Zeus VZ IgG IFA Test System
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Diamedix Microassay Test Set
Incstar Clin-ELISA Test System
Sigma EIA
Whittaker Bioproducts FIAX System
Whittaker Bioproducts VARICELISA II
Whittaker Bioproducts VARICELLA STAT
Speciality/Subspeciality: Hematology
Analyte: Activated Partial Thromboplastin Time (APTT)
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Manual coagulation assays
Analyte: Antithrombin III (ATIII)
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Behring Nor-partigen Kit
Helena Laboratories Quiplate System for RID
Kent Radial Immunodiffusion Test
Analyte: Fibrinogen
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:

Behring Nor-partigen Kit
Analyte: Hematocrit
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
Technicon H 6000
Technicon H1
Analyte: Hemoglobin
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
Technicon H 6000
Technicon H1
Analyte: Hemoglobin F
Test Category: Gel based immunochemical procedures
Test System, Assay or Examination:
Helena Laboratories Quiplate System for RID
Analyte: Platelet Count
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
Technicon H 6000
Technicon H1
Test Category: Manual cell counts
Test System, Assay or Examination: All Test Systems, Assays or Examinations
Analyte: Pleural Fluid Microscopic Elements
Test Category: Manual cell counts
Test System, Assay or Examination: All Test Systems, Assays or Examinations
Analyte: Prothrombin Time (PT)
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Manual coagulation assays
Analyte: Red Blood Cell Count (Erythrocyte Count)
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
Technicon H 6000
Technicon H1
Analyte: Reticulocyte Count
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
Sysmex R1000
Test Category: Manual reticulocyte counts
Test System, Assay or Examination: All Test Systems, Assays or Examinations
Analyte: White Blood Cell (WBC) Differential
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
Technicon H 6000
Technicon H1
Test Category: Manual white blood cell differential counts when the analyst is required to identify atypical cells
Test System, Assay or Examination:
All Test Systems, Assays or Examinations
Analyte: White Blood Cell Count (Leukocyte Count)
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
Technicon H 6000
Technicon H1
Speciality/Subspeciality:
Immunohematology
Analyte: ABH secretor status—Saliva
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Amtec Anti-H Lectin—qualitative
BCA Anti-H Lectin—qualitative
BCA Anti-H Lectin—quantitative
Dade Lectin-H—qualitative
Dade Lectin-H—quantitative
Gamma Anti-H Lectin—qualitative
Gamma Anti-H Lectin—quantitative
Analyte: ABO group—RBC
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
Gamma STS-M Automated Blood Grouping Instrument
Olympus PK1700 Automated Pretranfusion Blood Testing System
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Adsorption/Elution Procedures
Analyte: ABO group confirmation—Serum, Plasma
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
Gamma STS-M Automated Blood Grouping Instrument
Olympus PK1700 Automated Pretranfusion Blood Testing System
Analyte: D(Rho) Type
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
Gamma STS-M Automated Blood Grouping Instrument
Olympus PK1700 Automated Pretranfusion Blood Testing System
Analyte: Donor/Recipient Compatibility
Test Category: Compatibility testing including when performed to determine donor/recipient compatibility: recipient & donor ABO group/D(Rho) type/antigen typing, direct antiglobulin test, tests for unexpected antibody detection & identification, & crossmatch procedures
Test System, Assay or Examination: All Test Systems, Assays or Examinations
Analyte: Du (Weak D RBC antigen)
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination:
Olympus PK1700 Automated Pretranfusion Blood Testing System
Analyte: Fetal RBCs—Maternal Blood (fetal-maternal bleed)
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Du procedures with microscopic exam for mixed field agglut.
Gamma Fetal Bleed Screening Test
Indicator Cell Rosette Test
Ortho FETALSCREEN
Analyte: Isohemagglutinins
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Dade Neutr-AB Reagent—screen
Dade Neutr-AB Reagent—titration
Titration procedures
Analyte: RBC antigen type other than A or B
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Adsorption/Elution Procedures
Gamma Arachis hypogea Lectin
Gamma Lectin System
Analyte: Unexpected RBC antibody—detection—serum
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
1 Stage Enzyme Procedures
2 Stage Enzyme Procedures
Amtec Ficin Treated Screening Cells 1,2,3
Dade Rap-I.D. Polycation Potentiator System
Direct Antiglobulin Test (tube)
Gamma Ficin-Duet System
Gamma Ficin-Pool
Immucor Capture-R Ready-Screen

Immucor Panoscreen I and II, Ficin-Treated
Analyte: Unexpected RBC antibody—identification
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination: All Test Systems, Assays or Examinations
Speciality/Subspeciality: Mycobacteriology
Analyte: Acid-fast bacteria
Test Category: Antimycobacterial susceptibility testing
Test System, Assay or Examination: All Test Systems, Assays or Examinations
Test Category: Concentration, smear & primary culture inoculation
Test System, Assay or Examination: All Test Systems, Assays or Examinations
Test Category: Identification of Mycobacteria
Test System, Assay or Examination: Becton Dickinson Bactec NAP TB Differentiation Test
Test Category: Isolation and identification techniques
Test System, Assay or Examination: All Test Systems, Assays or Examinations
Analyte: Mycobacterium avium
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination: Manual Nucleic Acid analysis
Analyte: Mycobacterium avium complex
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination: Gen-Probe AccuProbe (w/culture)
Syngene Snap Culture ID Diagnostic Kit
Analyte: Mycobacterium avium specific
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination: Gen-Probe AccuProbe (w/culture)
Analyte: Mycobacterium gordonae
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination: Gen-Probe AccuProbe (w/culture)
Analyte: Mycobacterium intracellulare
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination: Manual Nucleic Acid analysis
Analyte: Mycobacterium intracellulare specific
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination: Gen-Probe AccuProbe (w/culture)
Analyte: Mycobacterium kansasii
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination: Gen-Probe AccuProbe (w/culture)
Analyte: Mycobacterium tuberculosis complex
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination: Gen-Probe AccuProbe (w/culture)
Manual Nucleic Acid analysis
Syngene Snap Culture ID Diagnostic Kit
Speciality/Subspeciality: Mycology
Analyte: All fungi
Test Category: Isolation and Identification of all fungi not specified in moderate complexity
Test System, Assay or Examination: All Test Systems, Assays or Examinations
Analyte: Blastomyces Dermatitidis
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination: Gen-Probe AccuProbe (w/culture)
Analyte: Coccidioides immitis
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination: Gen-Probe AccuProbe (w/culture)
Analyte: Cryptococcus
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination: Baxter MYCO–Immune Cryptococal Ag Latex Agg (semi-quant)
Gen-Probe AccuProbe (w/culture)
Meridian Cryptococcal Antigen Latex Agg. (semi-quant)
Meridian Diagnostics Premier Cryptococcal Ag (semi-quant)
Analyte: Histoplasma capsulatum
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination: Gen-Probe AccuProbe (w/culture)
Analyte: Systemic fungi
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination: Immuno-Mycologics Exo-Antigen ID System
Analyte: Yeast
Test Category: Automated or semi-automated procedures that do require operator intervention during the analytic process
Test System, Assay or Examination: Abbott Quantum II Yeast ID system
Test Category: Identification of Yeast not specified in moderate complexity
Test System, Assay or Examination: Analytab API 20C Yeast Identification Kits
Analytab API Germ Tube
Analytab Yeast Ident
Baxter MicroScan Rapid Yeast Identification Panel
Carr-Scarborough C. albicans Disc Screening Kit
Innovative Diagnostic Systems IDS Rapid SS/U System
Medical Wire Equip. MicroRing YT
Speciality/Subspeciality: Other
Analyte: Eye Cornea Integrity
Test Category: Eye bank microscopy procedures
Test System, Assay or Examination: Slit Lamp Biomicroscopy
Specular Microscopy
Speciality/Subspeciality: Parasitology
Analyte: Blood, tissue & intestinal parasites
Test Category: Concentration or differential stain techniques
Test System, Assay or Examination: All Test Systems, Assays or Examinations
Analyte: Intestinal parasites
Test Category: Antigen or toxin test procedures or kits requiring microscopic evaluations
Test System, Assay or Examination: Genetic Systems Pneumocystis Carinii IFA Test Kit
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination: Trend Scientific Giardia lamblia Direct Detection System
Speciality/Subspeciality: Toxicology/TDM
Analyte: Acetaminophen
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination: Syva Emit
Analyte: Amikacin
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination: Ames TDA
Syva Emit
Analyte: Carbamazepine
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination: Ames TDA
Syva Emit
Analyte: Carbamazepine, Free

Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Syva Emit
Analyte: Digoxin
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Syva Emit
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Abbott RIA Bead
Ciba Corning Magic (MGC)
Clinical Assays GammaCoat
Diagnostic Products Corp. Coat-a-Count
Sanofi/Kallestad Quanticoat
Ventrex Coated Tube
Analyte: Disopyramide
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Syva Emit
Analyte: Ethosuximide
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Ames TDA
Syva Emit
Analyte: Gentamicin
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Ames TDA
Syva Emit
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Clinical Assays GammaDab
Diagnostic Products Corp. Coat-a-Count
Analyte: Lidocaine
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Syva Emit
Analyte: Methotrexate
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Syva Emit
Analyte: N-Acetylprocainamide (NAPA)
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Ames TDA
Syva Emit
Analyte: Phenobarbital
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Ames TDA
Syva Emit
Analyte: Phenytoin
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Ames TDA
Syva Emit
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Clinical Assays GammaCoat
Analyte: Phenytoin, Free
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Syva Emit
Analyte: Primidone
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Ames TDA
Syva Emit
Analyte: Procainamide
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Ames TDA
Syva Emit
Analyte: Quinidine
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Ames TDA
Syva Emit
Analyte: Theophylline
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Ames TDA
Syva Emit
Test Category: Radioimmunoassays
Test System, Assay or Examination:
Clinical Assays GammaDab
Analyte: Tobramycin
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Ames TDA
Syva Emit
Analyte: Valporic Acid
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Ames TDA
Analyte: Valproic Acid
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Syva Emit
Speciality/Subspeciality: Virology
Analyte: Adenovirus
Test Category: Antigen or toxin test procedures or kits requiring microscopic evaluations
Test System, Assay or Examination:
Analytab Adenovirus Test Kit (IFA)
Cambridge Biotech Adenoclone (IFA)
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Analytab Adenovirus Test Kit (EIA) (culture confirmation)
Analytab Adenovirus Type 40 & 41 (EIA) (culture confirm)
Cambridge Biotech Adenoclone (EIA) (culture confirmation)
Analyte: All viruses
Test Category: Isolation and identification techniques
Test System, Assay or Examination: All Test Systems, Assays or Examinations
Analyte: Cytomegalovirus
Test Category: Antigen or toxin test procedures or kits requiring microscopic evaluations
Test System, Assay or Examination:
Baxter Bartels CMV Immediate Early Antigen IFA Test
Baxter Bartels Direct CMV Kit
Ortho CMV Identification Reagent
Syva Microtrak CMV Culture Identification Kit
Analyte: Herpes simplex
Test Category: Antigen or toxin test procedures or kits requiring microscopic evaluations
Test System, Assay or Examination:
Baxter Bartels HSV FA Monoclonal Antibody Kit
Baxter Bartels HSV FA Test for ID & Diff. HSV I & II
Diagnostic Products Corp. PathoDx Herpes Typing
Ortho Cultureset HSV Isolation and ID System
Ortho HSV 1 & 2 Dichromatic Typing Reagent
Sanofi/Kallestad Pathfinder H .simplex 1&2 D. Ant Det Sys
Syva Microtrak Syva HSV–1/HSV–2 Typing Test/Culture Confir
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Kodak SureCell (culture confirmation)
Wampole Virogen Herpes latex slide test (culture confirm)
Analyte: Respiratory syncitial virus
Test Category: Antigen or toxin test procedures or kits requiring microscopic evaluations
Test System, Assay or Examination:
Analytab Imagen RSV
Baxter Bartels RSV
Ortho RSV (IFA)

Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Sanofi/Kallestad Pathfinder RSV (spectrophotometric)
Analyte: Respiratory viruses (Influenza A&B, parainfluenza)
Test Category: Antigen or toxin test procedures or kits requiring microscopic evaluations
Test System, Assay or Examination:
Analytab IMAGEN Influenza—Virus A&B
Baxter Bartels Viral Respiratory Kit
Analyte: Rotavirus
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Abbott Rotazyme II Diagnostic Kit (photometric)
Sanofi/Kallestad Pathfinder Rotavirus (spectrophotometric)
Analyte: Varicella-Zoster viruses
Test Category: Antigen or toxin test procedures or kits requiring microscopic evaluations
Test System, Assay or Examination:
Ortho Varicella-Zoster Virus Identification Reagent
Analyte: Viruses
Test Category: Manual procedures with multiple steps in sample/reagent preparation or analytic process
Test System, Assay or Examination:
Manual Nucleic Acid analysis

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